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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

RON BERGMAN, Individually and on behalf
of all others similarly situated,

Plaintiff,

v.

CARIBOU BIOSCIENCES, INC., RACHEL
E. HAURWITZ, JASON V. O'BYRNE,
RYAN FISCHESSE, SCOTT
BRAUNSTEIN, ANDREW GUGGENHIME,
JEFFREY LONG-MCGIE, NATALIE R.
SACKS, BOFA SECURITIES INC.,
CITIGROUP GLOBAL MARKETS, INC.,
and SVB SECURITIES LLC,

Defendants.

Case No. 23-cv-01742

CLASS ACTION

**AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

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1 Court-appointed Lead Plaintiff Ron Bergman and named plaintiff Carl D. Cooper
 2 (“Plaintiffs”), individually and on behalf of all others similarly situated, by Plaintiffs’
 3 undersigned attorneys, allege in this amended complaint the following upon knowledge with
 4 respect to their own acts, and upon facts obtained through an investigation conducted by their
 5 counsel, which included *inter alia*, review and analysis of: (i) Defendant Caribou Biosciences,
 6 Inc.’s (“Caribou,” or the “Company”) filings with the Securities and Exchange Commission
 7 (“SEC”); (ii) information concerning Caribou from the U.S. Food and Drug Administration
 8 (“FDA”); (iii) in-depth research reports by securities and financial analysts concerning Caribou;
 9 (iv) transcripts of Caribou’s conference calls with analysts and investors; (v) presentations, press
 10 releases, and media reports regarding Caribou; (vi) data concerning Caribou’s stock price; and
 11 (vii) other information readily obtainable on the Internet. Plaintiffs believe that substantial
 12 additional evidentiary support will exist for the allegations set forth herein after a reasonable
 13 opportunity for discovery. Most of the facts supporting these allegations are known only by
 14 Defendants (defined below), or are exclusively within their or control.¹

15 I. INTRODUCTION

16 1. This is a federal securities class action on behalf of all persons and entities who
 17 purchased Caribou common stock from between July 23, 2021 and July 13, 2023, both dates
 18 inclusive (“Class,” and the period from July 23, 2021 through July 13, 2023 is the “Class
 19 Period”).² Plaintiffs bring the following claims on behalf of the Class: (1) claims pursuant to §§
 20 11 and 15 of the Securities Act of 1933 (“Securities Act”) for all persons and entities who
 21

22 ¹ Pursuant to the Court’s Standing Order for Civil Cases, Section VII, A., attached hereto as
 23 Exhibit A is a red-line document showing the changes made to the previously filed complaint
 (Dkt. No. 1).

24 ² Excluded from the Class are: (a) persons who suffered no compensable losses; and (b)
 25 Defendants (defined *infra*); the present and former officers and directors of the Company at all
 26 relevant times; members of their immediate families and their legal representatives, heirs,
 27 successors, or assigns, and any entity in which any of the Defendants, or any person excluded
 under this subsection (b), has or had a majority ownership interest at any time.

1 purchased Caribou common stock pursuant or traceable to the Company’s registration statement
 2 and prospectus (collectively, the “Offering Documents”) issued in connection with the
 3 Company’s initial public offering (the “IPO” or “Offering”) conducted on or about July 23, 2021;
 4 and (2) claims pursuant to §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C.
 5 §§78j(b) and 78t(a) (the “Exchange Act”), for all persons or entities who purchased Caribou
 6 common stock during the Class Period at artificially inflated prices and were damaged when the
 7 artificial inflation dissipated upon a series of corrective disclosures.³

8 2. Founded in 2011, Caribou is a clinical-stage biopharmaceutical company that
 9 engages in developing gene-edited cell therapies to treat solid tumors and hematologic
 10 malignancies. Caribou applies its CRISPR (Clustered Regularly Interspaced Short Palindromic
 11 Repeats; pronounced “crisper”) platform called, CRISPR hybrid RNA-DNA, or chRDNA,
 12 (pronounced “chardonnay”) to develop these genome edited cell therapies. Caribou’s chRDNA
 13 technology uses an RNA-DNA hybrid to “edit” cells. In simple terms, gene editing works by
 14 changing a DNA sequence. In CRISPR genome editing, a CRISPR molecule finds a precise
 15 location in the target DNA, a CRISPR enzyme cuts the DNA at that point, and then, an “edit” is
 16 made where a new custom sequence is added when the DNA is repaired.⁴ The Company’s most
 17 advanced product candidate is CB-010, an allogeneic, or “off-the-shelf”, anti-CD19 chimeric
 18 antigen receptor (“CAR”)-T cell therapy that is in a Phase 1 clinical trial (“ANTLER” or
 19 “ANTLER Trial”) to treat relapsed or refractory B cell non-Hodgkin lymphoma (“r/r B-NHL”).⁵

20 3. Historically, CAR-T cell therapies have been “autologous”, meaning that cancer-
 21 destroying T cells are taken from a patient’s own blood, changed in the lab by adding a CAR to
 22

23 ³ Unless otherwise noted, internal citations are omitted and emphasis is added throughout.

24 ⁴ Innovative Genomics Institute, *What is CRISPR?* (2023)
<https://innovativegenomics.org/education/digital-resources/what-is-crispr/>.

25 ⁵ CAR-T cell therapy is a way to get immune cells called *T cells* (a type of white blood cell) to
 26 fight cancer by changing them in the lab so they can find and destroy cancer cells. CAR-T cell
 27 therapy is also sometimes talked about as a type of *cell-based gene therapy* because it involves
 altering the genes inside T cells to help them attack the cancer.

1 help the T cells attach to a specific cancer cell antigen, and then injected back into the patient.
 2 While autologous cell therapies have demonstrated durability because they are derived from a
 3 patient's own cells (and thus are not as likely to be rejected by the patient's immune system),
 4 they are expensive and time-intensive because they are customized for each patient.

5 4. By contrast, allogeneic or "off-the-shelf" cell therapies are derived from donor
 6 cells. Allogeneic cell therapies hold the promise of lower cost and quicker turnaround time.
 7 However, allogeneic cell therapies have not demonstrated significant and reproducible efficacy
 8 in solid tumors. Specifically, allogeneic CAR-T projects have struggled to yield lasting complete
 9 responses or "CRs". In cancer treatment, CR refers to the absence of all detectable cancer post
 10 treatment, whereas durability or durable response refers to the amount of time a patient remains
 11 in remission and does not relapse. In the area of gene-edited cell therapies used to treat cancer,
 12 six-month durability has emerged as the minimum for patient remission to be considered "real."
 13 Defendants, as experts in the industry, were aware of this six-month minimum durability
 14 threshold at all relevant times.

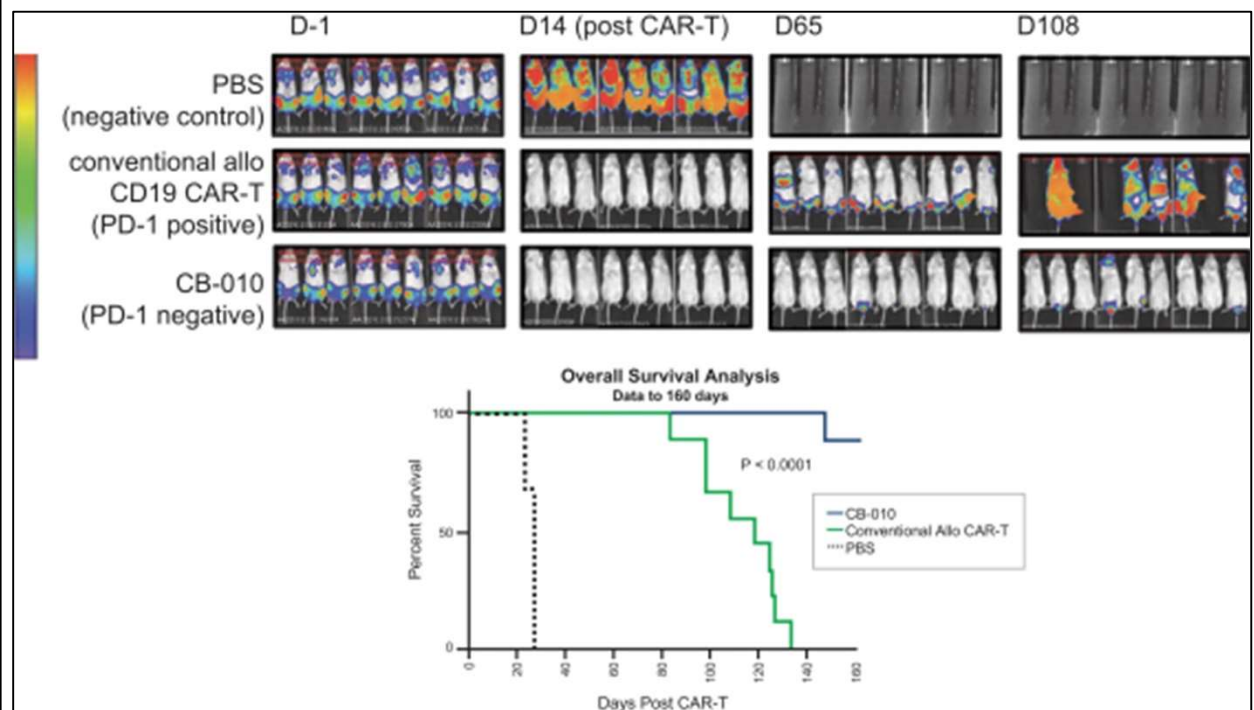
15 5. In order to improve durability, Caribou purportedly designed CB-10 using three
 16 CRISPR edits: "1) we knock out the TRAC gene to remove the T cell receptor, 2) we site-
 17 specifically insert an anti-CD19 CAR into the trac gene, and 3) we knock out PD-1." According
 18 to Caribou, the last of these three steps, removing or "knocking out" the programmed cell death
 19 protein 1 ("PD-1") from the CAR-T cell surface by a genome-edited knockout of the *PDCDI*
 20 gene, purportedly "boosted" antitumor activity.

21 6. To help fund its operations, Caribou raised nearly \$300 million in an initial public
 22 offering ("IPO") of its shares. On July 1, 2021, the Company filed a registration statement on
 23 Form S-1 with the SEC, in connection with its IPO, which, after several amendments, was
 24 declared effective by the SEC on July 22, 2021 (the "Registration Statement"). The Registration
 25 Statement represented that Caribou was using its "chRDNA technology to **enhance, or armor,**
 26
 27

our cell therapies” – including CB-010 which targeted CD19.⁶ Caribou touted CB-010 as the “*first* clinical-stage allogeneic anti-CD19 CAR-T cell therapy.”

7. The Registration Statement further represented, that “[w]e have *demonstrated in preclinical models* that the PD-1 knockout improves the persistence of antitumor activity.” Specifically, the Company’s “*preclinical in vivo data from experiments conducted in mouse xenograft models ... demonstrate that knocking out PD-1 leads to a significant increase in the durability of antitumor activity.*”

8. As support for what Caribou had “demonstrated,” the Registration Statement provided the graphic below showing the tumor activity in mice up to day 108 of the study and survival data for the mice up to day 160 or 5.3 months of the study:



9. In addition, the Registration Statement represented that the Company’s *in vitro*

⁶ Because different cancers have differing antigens, each CAR is made for a specific cancer’s antigen. In certain kinds of leukemia or lymphoma, the cancer cells have an antigen called CD19. The CAR-T cell therapies that treat cancers with the CD19 antigen are made to attach to the CD19 antigen and will not work for a cancer that does not have the CD19 antigen.

1 studies showed that “CB-010 cells demonstrate *dose-dependent* and robust cytotoxic⁷ activity at
2 a range of effector-to-target ratios compared to negative control cells.” In other words, when CB-
3 010 was administered at higher doses, its ability to fight cancer cells purportedly increased.

4 10. On July 23, 2021, Caribou’s common stock began publicly trading under the
5 ticker symbol “CRBU” on the Nasdaq Global Select Market (“NASDAQ”). That same day,
6 Caribou filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which
7 incorporated and formed part of the Registration Statement (the “Prospectus”).

8 11. Pursuant to the Offering Documents, Caribou issued 19 million shares of common
9 stock at the Offering price of \$16.00 per share raising proceeds of \$282.72 million for the
10 Company, before expenses, and after applicable underwriting discounts.

11 12. Defendants BofA Securities Inc. (“BofA”), Citigroup Global Markets, Inc.
12 (“Citigroup”), and SVB Securities LLC (formerly known as SVB Leerink LLC) (“SVB”) served
13 as underwriters, selling 6,935,000, 6,365,000 and 5,700,000 shares, respectively, in the IPO and
14 received a total of \$24,472,000 in underwriting commissions.

15 13. The Offering Documents contained untrue statements of material fact and/or
16 omitted to state other facts necessary to make the statements made therein not misleading.
17 Specifically, in the Offering Documents, Defendants (defined *infra*) made false or misleading
18 statements and omitted that: (i) CB-010’s design was not an improvement on competitors’
19 designs because knocking out the PD-1 protein would not significantly increase the durability of
20 antitumor activity in humans; (ii) as a result, escalated dosing of CB-010 would not improve its
21 durability in a clinical trial; and (iii) Caribou was not the first to conduct a clinical trial of an
22 allogeneic CAR-T cell therapy knocking out the PD-1 protein; in fact, results from a Phase I
23 study had come out two months prior to Caribou’s IPO which undermined its proposition that
24 knocking out PD-1 was linked to enhanced clinical performance. Accordingly, in the Offering
25 Documents, Defendants overstated CB-010’s clinical and commercial prospects and omitted the

26
27 ⁷ Cytotoxic refers to a treatment’s ability to kill cancer cells.

1 trends then facing Caribou's business, in contravention of the specific disclosure requirements
2 of the federal securities laws.

3 14. Additionally, throughout the Class Period, and following Caribou's IPO,
4 Defendants Caribou, its Chief Executive Officer ("CEO") Rachel Haurwitz, and its Chief
5 Financial Officer ("CFO") Jason O'Byrne (collectively, the "Exchange Act Defendants")
6 continued to misrepresent its preclinical and clinical studies and CB-010's commercial prospects.

7 15. Following the IPO, Caribou's competitors – whose clinical trials were ahead of
8 CB-010 – began posting their clinical trial results. On December 13, 2021, Allogene
9 Therapeutics, Inc. ("Allogene") published updated data from its two Phase 1 clinical trials of its
10 lead anti-CD19 AlloCART T therapy programs which were "'on par' with autologous CAR T
11 therapy". Allogene reported no relapses in large B cell lymphoma ("LBCL") CAR-T naïve
12 patients across trials who had achieved a CR *at six months* and a 44% CR rate with ongoing CRs
13 *at nine months*. On June 6, 2022, Adicet Bio, Inc. ("Adicet") announced updated data from the
14 Phase 1 study of its a CAR T cell therapy for r/r B-NHL showing 75% CR across all dose levels
15 and 50% of evaluable patients *with at least six months follow-up* remaining cancer-free,
16 indicating "durable anti-tumor responses with potential for dose related increase in durability."
17 And on June 8, 2022, Precision Biosciences, Inc. ("Precision") announced new clinical data for
18 its CD19 CAR T therapy showing a 73% CR rate among evaluable relapsed patients and a 50%
19 durable response rate *greater than six months*.

20 16. During the Class Period, Caribou represented that CB-010 was at least on par with
21 its autologous predecessors. For example, on May 12, 2022, the Company released initial results
22 from its Phase 1 trial showing an 80% CR rate as of the February 23, 2022 data cutoff date. And
23 that patients with a CR at 28 days had maintained it at three months. Even though the cutoff date
24 for six-month data would be available the very next day, and interim data was already available,
25 Caribou chose to release this 28-day data. Caribou CEO Haurwitz then put the data in perspective
26 with respect to FDA-approved autologous therapies, stating "that the approved CAR-Ts that
27

1 focus on CD19-positive disease have achieved overall response rates of about 50% to 70% and
2 overall response rates of 30% to 50%. These include Gilead's Yescarta, Bristol Myers Squibb's
3 Breyanzi and Novartis' Kymriah." In response to these and other Company statements that day,
4 the Company's stock surged 27%.

5 17. But before markets opened on June 10, 2022, Caribou reported updated results
6 from its Phase 1 trial revealing that "[a]t 6 months following the single dose of CB-010, [only]
7 40% of patients remained in CR (2 of 5 patients) as of the May 13, 2022 data cutoff date[.]"
8 prompting investor concern over the Company's ability to demonstrate CB-10's durability.

9 18. On this news, Caribou's stock price fell 41.5%, on heavy trading volume to close
10 at \$5.10 per share on June 13, 2022.

11 19. Despite this, Caribou continued to assure investors that CB-010's unique
12 mechanism of action boosted anti-tumor activity and would yield durable responses, encouraging
13 investors to wait for more data, especially considering that Caribou would soon start the dose
14 escalation portion of the ANTLER Trial, where patients continuing in the trial would be
15 administered higher doses of CB-010. Haurwitz, in particular, continued to assure investors that
16 CB-010's "long-term durability at dose level 1 is comparable to autologous cell therapies."

17 20. Then, on July 13, 2023, Caribou reported "long-term follow-up data from the dose
18 escalation portion of the ongoing ANTLER Phase 1 trial," including that in three subjects given
19 120 million cells, there was one non responder and only two remissions, which lasted less than
20 three months. Patients thus continued relapsing, despite receiving higher doses, indicating that
21 CB-10 was not in fact dose-dependent, and was no more effective or durable at even triple the
22 initial dose. In addition, for the first time, Caribou cautioned against accepting its Class Period
23 statements comparing its results to its competitors' results at face value because it "has not
24 performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-
25 010, and Caribou has only reviewed publicly available reports of those trials. As such, the results
26 of these other clinical trials may not be comparable to clinical results for CB-010."
27

21. On this news, Caribou's stock price fell 22.6% on heavy trading to close at \$6.30 per share on July 14, 2023.

22. As of the time this Amended Complaint was filed, Caribou common stock continues to trade below the \$16.00 per share Offering price, damaging investors.

23. In this Complaint, Plaintiffs assert two distinct sets of claims on behalf of themselves and the putative Class, as discussed below.

24. Counts One and Two assert securities fraud-based claims under §§ 10(b) and 20(a) of the Exchange Act against the Exchange Act Defendants (the "Exchange Act Claims"). Plaintiffs' Exchange Act claims arise out of a fraudulent or deliberately reckless course of business conduct whereby, throughout the Class Period, the Exchange Act Defendants knew or recklessly disregarded that: (i) the statements and omissions they made, as alleged herein, were materially false and misleading; (ii) their statements would adversely affect the integrity of the market for Caribou securities; and (iii) their statements would deceive investors into purchasing shares of Caribou securities at artificially inflated prices, including in the Company's \$282 million IPO which closed on July 23, 2021.

25. Specifically, the Exchange Act Defendants knowingly or recklessly made materially false and misleading public statements and omitted that: (i) CB-010's design was not an improvement on competitors' designs because knocking out the PD-1 protein would not significantly increase the durability of antitumor activity in humans; (ii) as a result, CB-010's treatment effect would not improve with escalated dosing in humans; (iii) Caribou's competitors had already achieved results comparable to early autologous CAR-T trials; (iv) Caribou was not the first trial of an allogeneic CAR-T cell therapy that removed PD-1 from the CAR-T cell surface by a genome-edited knockout of the *PDCDI* gene; in fact, results from a prior trial undermined Caribou's proposition that knocking out PD-1 improved durability; and (v) as a result, the Exchange Act Defendants' positive statements about Caribou's preclinical and clinical studies and prospects were materially misleading and lacked a reasonable basis.

26. Counts Three and Four assert strict liability, non-fraud claims, under §§ 11 and 15 of the Securities Act against Caribou and the Securities Act Defendants (defined below) (the “Securities Act Claims”). The Securities Act claims arise from the Securities Act Defendants negligently making materially false and misleading statements and omissions in the Offering Documents issued in connection with the Company’s IPO. The Securities Act claims are not based on any allegation of deliberate or intentional misconduct, and Plaintiffs expressly disclaim any reference or reliance upon fraud allegations for such claims.

27. As set forth herein, each Securities Act Defendant negligently made materially false and misleading statements and omissions in the IPO Documents that: (i) mischaracterized Caribou’s ability to demonstrate durability in its Phase 1 trial of CB-010 by touting the durability demonstrated by its preclinical trial of CB-010 in mice without providing tumor data past 108 days and survival data past 160 days; (ii) negligently promoted the CB-010 program as having been “demonstrated in preclinical models” to “improve[] the persistence of antitumor activity” while disregarding mice tumor data past 108 days and mice survival data past 160 days; (iii) negligently omitted that Caribou’s competitors had already achieved results comparable to early autologous CAR-T trials; and (iii) failed to adequately warn investors that certain “Risk Factors” listed in the IPO Documents had already materialized at the time of the IPO. At that time, the Company’s preclinical data had failed to adequately demonstrate durability and thus, patients would continue relapsing even when CB-010 was given at higher doses.

II. JURISDICTION AND VENUE FOR PLAINTIFFS’ EXCHANGE ACT CLAIMS

28. Counts One and Two arise under §§ 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5 (“Rule 10b-5”).

29. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act because this is a civil action arising under U.S. laws.

30. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act and 28 U.S.C. § 1391(b)-(d). Specifically, Caribou is headquartered in this Judicial District,

1 Defendants conduct business in this Judicial District, and a significant portion of Defendants’
2 activities took place within this Judicial District.

3 31. In connection with the acts, transactions, and conduct alleged herein, Defendants,
4 directly or indirectly, used the means and instrumentalities of interstate commerce, including,
5 but not limited to, the U.S. mail, interstate telephone and other electronic communications, and
6 the facilities of the NASDAQ, a national securities exchange.

7 **III. PARTIES**

8 **A. Plaintiffs**

9 32. Lead Plaintiff Bergman, as set forth in his PSLRA certification filed with the
10 Court (Dkt. No. 11-3) and incorporated by reference herein, purchased shares of Caribou
11 common stock traceable to Company’s Registration Statement and was damaged thereby.

12 33. Named plaintiff Carl D. Cooper, as set forth in his certification filed herewith,
13 purchased Caribou common stock at artificially inflated prices during the Class Period and was
14 damaged upon the revelation of the corrective disclosures alleged herein.

15 **B. Exchange Act Defendants**

16 1. Corporate Defendant Caribou

17 34. Defendant Caribou is a Delaware corporation with principal executive offices
18 located at 2929 7th Street, Suite 105, Berkeley, California 94710. The Company’s common stock
19 trades under the ticker symbol “CRBU” in an efficient market on the NASDAQ.

20 2. Executive Defendants

21 35. Defendant Rachel E. Haurwitz (“Haurwitz”) co-founded Caribou and has served
22 as its President, CEO, and a director since its inception in 2011. Haurwitz signed the Registration
23 Statement filed with the SEC as Attorney-in-Fact for Caribou.

24 36. Defendant Jason V. O’Byrne (“O’Byrne”) served as Caribou’s CFO throughout
25 the Class Period and has been responsible for its finance and investor relations functions since
26 2021. O’Byrne signed the Registration Statement filed with the SEC.

37. Defendants Haurwitz and O’Byrne are sometimes referred to herein collectively as the “Exchange Act Individual Defendants.”

38. The Exchange Act Individual Defendants possessed the power and authority to control the contents of Caribou’s SEC filings, press releases, and other market communications. The Exchange Act Individual Defendants were provided copies of Caribou’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause their correction. Because of their positions with Caribou, and access to material information available to them but not the public, the Exchange Act Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then false and materially misleading. The Exchange Act Individual Defendants are liable for the misstatements and omissions pleaded herein.

39. Caribou is liable for the wrongful acts alleged herein of the Individual Defendants (defined *infra*) and its employees under the doctrine of *respondeat superior* and common law principles of agency because all such acts were carried out within the scope of their employment.

40. Caribou and the Exchange Act Individual Defendants are sometimes referred to herein collectively as the “Exchange Act Defendants.”

IV. SUMMARY OF THE EXCHANGE ACT DEFENDANTS’ FRAUD

A. Caribou’s Founding and Relevant Background

41. Caribou is a clinical-stage biopharmaceutical company co-founded in 2011 by Jennifer Doudna, Ph.D., and Defendant Haurwitz, pioneers in CRISPR genome editing. CRISPR “refers to the way bacteria store, in their genomes, snippets of viral DNA, like mug shots. Those markers are used to identify invaders that return, much as a human immune system uses telltale elements of a poliovirus remembers from a vaccine.”⁸

⁸ Avisol Capital Partners, *Caribou Bioscience: Gene Editing Pioneer Files IPO To Raise \$100M*, SEEKING ALPHA (Jul. 11, 2021 5:16AM ET), <https://seekingalpha.com/article/4438629-caribou-bioscience-gene-editing-pioneer-files-ipo-to-raise-100m-crpu> (“7/11/21 SA Article”).

42. Caribou has been applying its CRISPR platform, chRDNA, toward developing genome-edited *allogeneic* cell therapies for the treatment of hematologic malignancies and solid tumors. Within the immune system, white blood cells like T cells are responsible for defending the body against pathogens and abnormal cells, including cancer cells. *Autologous* CAR-T cell therapies have proven successful in fighting cancer cells, but they involve modifying a patient's own T cells to express a particular CAR, growing those cells outside the patient's body to expand their numbers, and then infusing them back into the patient to recognize and destroy cancer cells in a targeted manner. This is time consuming (processing of cells and tissues requires time, and there is a significant lag before the commencement of treatment in some procedures), expensive, and not feasible for patients whose own stem cells are ineligible for transplant due to hematological malignancies. Universal allogeneic cell therapies do not require bridging therapy while T cells are growing and have the potential to provide broader patient access, off-the-shelf availability, more efficient and cost-effective manufacturing, and more potent and persistent treatment outcomes. The allogeneic model is also far more financially appealing to biopharmaceutical companies like Caribou because it does not involve the costly service component of autologous therapies, and offers the potential to scale production.

43. Caribou's lead product candidate is CB-010, an allogeneic anti-CD19 CAR-T cell therapy that received investigational new drug ("IND") clearance from the FDA in September 2020 and is being evaluated in the ANTLER Phase 1 clinical trial as a treatment for r/r B-NHL.

44. PD-1 is a protein on the surface of T and B cells that has a role in regulating the immune system's response to the cells of the human body by down-regulating the immune system and promoting self-tolerance by suppressing T cell inflammatory activity. The molecule, or ligand, that bonds to PD-1 (PD-L1) is highly expressed in several cancers and essentially prevents the immune system from killing cancer cells. The PD-1 protein is encoded on the PDCD1 gene.

45. Caribou touted CB-010 as the first allogeneic CAR-T cell therapy that removed

the PD-1 from the CAR-T cell surface by a genome-edited knockout of the *PDCD1* gene, which purportedly boosts antitumor activity.

46. CB-010's development and approval was Caribou's single most important treatment and indisputably its material, core operation that directly drove the Company's stock price throughout the Class Period. As market analysts noted, CB-010 "could possibly change the potential treatment landscape for CAR-T."⁹ Accordingly, a "major catalyst" for the Company was "the release of additional results from the phase 1 ANTLER study by the end of 2022." *Id.* Premier healthcare investors like AbbVie Ventures and The Leukemia & Lymphoma Society Therapy Acceleration Program specifically directed their investments in the Company toward advancing CB-010.¹⁰ If approved, revenue for CB-010 is expected to reach an annual total of \$168 million by 2037 globally based off GlobalData's Expiry Model.¹¹ The fact that Caribou's future financial prospects were so intimately intertwined with CB-010's regulatory and commercial success supports a finding of the Exchange Act Defendants' scienter.

47. One of Caribou's key competitors is Allogene. Like Caribou, Allogene uses MaxCyte's electroporation technology to accomplish multiple genomic edits, but unlike Caribou, Allogene uses a gene editing tool called TALEN.¹² The market appears to recognize the similarity between of Caribou's and Allogene's respective therapies, as reflected in the "sympathetic detonation" of Caribou's stock price from a high of \$24 a share to a low of \$18 a share – a nearly 25% drop – after the FDA placed a clinical hold on Allogene's clinical trials on

⁹ Chrisomalis, Terry, *Caribou Biosciences: Potential to Change CAR-T Landscape*, SEEKING ALPHA (Aug. 1, 2022 2:19PT ET), <https://seekingalpha.com/article/4528312-caribou-biosciences-potential-to-change-car-t-landscape> ("8/1/22 SA Article").

¹⁰ 7/11/21 SA Article.

¹¹ GlobalData, *Risk adjusted net present value: What is the current valuation of Caribou Biosciences's CB-010*, PREMIUM INSIGHTS (Sept. 11, 2023), <https://www.pharmaceutical-technology.com/data-insights/cb-010-caribou-biosciences-net-present-value/?cf-view>.

¹² Avisol Capital Partners, *Caribou Biosciences: Another Gene Editor Hurt By the Allogene Hold*, SEEKING ALPHA (OCT. 12, 2021 4:15PM ET), <https://seekingalpha.com/article/4459565-caribou-biosciences-stock-another-gene-editor-hurt-by-allogene-hold> ("10/12/21 SA Article").

October 7, 2021. *Id.* The FDA lifted the hold by January 10, 2022, putting Allogene back in the race with Caribou to achieve durability in the allogeneic space.¹³

48. To-date however, allogeneic CAR-T cell therapies still have not demonstrated significant and reproducible efficacy in solid tumors.¹⁴ Since allogeneic CAR-T projects have struggled to yield lasting complete responses (“CRs”), six-month durability has emerged as the minimum for patient remission to be considered real.¹⁵

B. Caribou’s Blockbuster IPO

49. In connection with its IPO, Caribou filed a Registration Statement on Form S-1 with the SEC on July 1, 2021.¹⁶ Caribou subsequently amended the Registration Statement twice and requested that the SEC declare it effective on an accelerated basis. Following its standard practice, the SEC acceded and on July 22, 2021, the Registration Statement went into effect.

50. As a result, on July 23, 2021, pursuant to the Registration Statement, Caribou’s common stock began publicly trading on the NASDAQ. That same day, Caribou filed the Prospectus with the SEC, which incorporated and formed part of the Registration Statement.¹⁷

51. The Prospectus discouraged investors from doing their own due diligence by instructing them to rely on the information provided or incorporated into that document: “We and the underwriters have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or in any free writing

¹³ Avisol Capital Partners, *Allogene: Leading The Allogeneic CAR-T Space, Again*, SEEKING ALPHA (Apr. 1, 2022 5:41PM ET), <https://seekingalpha.com/article/4499347-allogene-allo-leading-allogeneic-car-t-space>.

¹⁴ Caribou Biosciences, Inc., Form 10-K for the fiscal year ending December 31, 2021 (Mar. 21, 22), <https://investor.cariboubio.com/node/7271/html> (“2021 10-K”) at 8.

¹⁵ Plieth, Jacob, *Caribou’s allogeneic Car meets a six-month bar*, EVALUATE VANTAGE (Jul. 14, 2023), <https://www.evaluate.com/vantage/articles/news/trial-results/caribous-allogeneic-car-meets-six-month-bar> (“7/14/23 EV Article”).

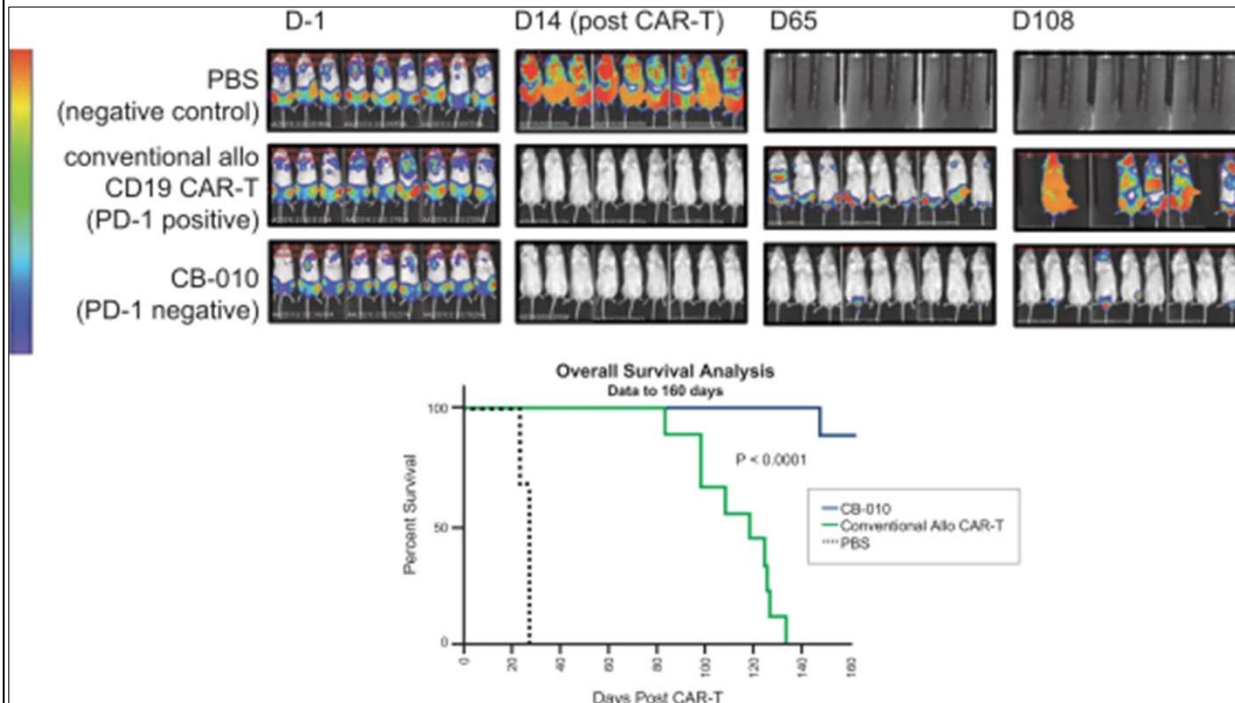
¹⁶ Caribou Biosciences, Inc., Form S-1 Registration Statement (Jul. 1, 2021), <https://investor.cariboubio.com/node/6431/html> (“Registration Statement”).

¹⁷ Caribou Biosciences, Inc., Prospectus (Jul. 23, 2021), <https://investor.cariboubio.com/sec-filings/sec-filing/424b4/0001193125-21-223038> (“Prospectus”).

prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.” The Prospectus further told investors to “not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.”

52. Pursuant to the Offering Documents, Caribou issued 19 million shares of common stock to the public at the Offering price of \$16.00 per share for proceeds of \$282.72 million to the Company, before expenses, and after applicable underwriting discounts. The IPO thus valued Caribou at a whopping \$907.3 million.

53. The Offering Documents touted CB-010 as the “*first* clinical-stage allogeneic anti-CD19 CAR-T cell therapy,” represented that Caribou “ha[s] *demonstrated* in preclinical models that the PD-1 knockout [effect of CB-010] improves the persistence of antitumor activity,” and from those models, provided mice tumor activity up to day 108 and survival data up to day 160 or 5.3 months:



54. The Offering Documents further represented that “by day 108 following dosing, half the mice treated with the conventional allogeneic CD19 CAR-T cell therapy had expired

1 from their recurrent tumor burden, and the surviving mice in that cohort had metastatic disease.
 2 In contrast, by day 108 following dosing, all of the CB-010-treated mice were alive and roughly
 3 half had no detectable tumor burden ... all of the mice treated with the conventional allogeneic
 4 CD19 CAR-T cells had succumbed to their tumors by approximately day 135, while all but one
 5 of the CB-010 treated mice were still alive by day 160.”

6 55. With respect to the purported durability of CB-010’s treatment effect, the
 7 Offering Documents specifically stated, in relevant part, that “preclinical in vivo data from
 8 experiments conducted in mouse xenograft models submitted as part of our CB-010 IND
 9 [Application] **demonstrate** that knocking out PD-1 leads to a significant increase in the durability
 10 of antitumor activity and therefore overall mouse survival.”

11 56. And with respect to the purported efficacy of CB-010’s treatment, the Offering
 12 Documents touted that “We use our chRDNA technology to **enhance, or armor**, our cell
 13 therapies by creating additional genomic edits to improve persistence of antitumor activity.”

14 57. The Registration Statement also disclosed as a “risk factor” the names of
 15 Caribou’s competitors. While maintaining that its technology was superior, it disclosed the
 16 names of other companies developing CRISPR-based technologies:

17 Compared to first generation genome-editing approaches, our chRDNA platform
 18 has shown improved specificity, a reduction in off-target edits and translocations
 19 and advanced capability to perform multiplexed edits, in particular multiplexed
 20 insertions. While we believe that our scientific expertise, novel technology, and
 21 intellectual property position offer competitive advantages, we face competition
 22 from multiple other genome-editing technologies and companies. Other companies
 23 developing CRISPR-based technologies include, among others, Beam
 24 Therapeutics Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Intellia
 25 Therapeutics, Inc., Metagenomi Technologies, LLC, Poseida Therapeutics, Inc.,
 26 and Scribe Therapeutics, Inc. Companies developing other genome-editing
 27 technologies include, among others, Allogene Therapeutics, Inc., bluebird bio, Inc.,
 Collectis S.A., Precision BioSciences, Inc., and Sangamo Therapeutics, Inc.

We believe that our CAR-T cell therapy product candidates have the potential to offer a superior product to patients due to genome edits we make to improve their persistence with the goal of extending robust CAR-T cell antitumor activity in patients.

58. Analysts focused on the Offering Documents’ statements about the Company’s

“demonstrat[ion] in preclinical models”¹⁸ and “refer[ence] to its process as ‘armoring’ the cells”¹⁹ in promoting the IPO.

59. Further, the Registration Statement noted that the Company’s *in vitro* studies showed that “CB-010 cells demonstrate **dose-dependent** and robust cytotoxic activity at a range of effector-to-target ratios compared to negative control cells.” Accordingly, investors understood that CB-010’s treatment effect would be more durable as doses were escalated.

C. Unbeknownst to Investors, Prior to the IPO, Caribou Executives Knew that Competitors Had Already Achieved Results Comparable to Early Autologous Car-T Treatments.

60. According to the Offering Documents, the Company’s preclinical data showed statistically significant improvement in survival of mice that received CB-010 treatment compared to control groups that did not. The preclinical study involved engrafting mice with acute leukemia, waiting 23 days before commencing treatment, and then testing the mice in three separate treatment groups as follows: (1) a control saline; (2) conventional allogeneic CD19 CAR-T cells, *i.e.* T cells with the anti-CD19 CAR used in CB-010 inserted into the TRAC locus, but without the PD-1 knockout, or (3) CB-010.

61. Although preclinical studies on mice are common, scientists have noted that they are limited in their ability to mimic the extremely complex process of human carcinogenesis, physiology, and progression.²⁰

62. On September 8, 2020, Caribou announced that the FDA had cleared the Company’s IND Application for CB-010, which had included its preclinical mice study in its

¹⁸ Jones, Donovan, *Caribou Biosciences Aims for \$255 Million IPO*, SEEKING ALPHA (Jul. 22, 2021), <https://seekingalpha.com/article/4440683-caribou-biosciences-aims-for-255-million-ipo> (“7/22/21 SA Article”).

¹⁹ Hawthorne, Jason, *3 Reasons Caribou Biosciences Could Be the Best Gene-Editing Stock for Your Portfolio*, THE MOTLEY FOOL (Jul. 27, 2021) (“7/27/21 Motley Article”).

²⁰ Kelder, Regina, *The Evolving Mouse Model in Cancer Research*, EUREKA, (Jul. 10, 2023), <https://www.criver.com/eureka/evolving-mouse-model-cancer-research#:~:text=But%20mouse%20models%20also%20have,overall%20translatability%20to%20the%20clinic> (“7/10/23 Eureka Article”).

1 data package, and the Company would begin its clinical trials of CB-010.

2 63. On October 21, 2020, a Caribou competitor also focusing on allogeneic cell
3 therapy, CRISPR Therapeutics AG (“CRISPR”) released top-line results from its ongoing Phase
4 1 CARBON trial of CTX110, an allogeneic CAR-T cell therapy targeting CD19+ B-cell
5 malignancies. The results showed CR rates of 33%, 50%, and 100% at dose levels 2, 3, and 4,
6 respectively, at three months. These results “show[ed] dose dependent efficacy and response
7 rates that are comparable to the early autologous CAR-T trials.”²¹

8 64. On June 4, 2021, Allogene released updated data for its allogeneic gene-editing
9 treatment for non-Hodgkin lymphoma, which showed a six-month CR rate of 36% in CAR T
10 naïve LBCL patients treated with ALLO-501 and a “CR rate of 50% across [LBCL and follicular
11 lymphoma] histologies in CAR T naïve patients on par with autologous CAR T therapies.”²²

12 65. In the Offering Documents, however, the Exchange Act Defendants directed
13 investors to ignore outside materials. Despite being aware of clinical data directly relevant to
14 investors’ ability to assess Caribou’s commercial prospects and thereby decide whether to invest
15 in its stock, the Exchange Act Defendants omitted to disclose this material information and
16 dissuaded investors from learning of at least some of the truth concealed by the
17 misrepresentations and omissions in the Offering Documents.

18 66. Haurwitz, in particular, during the first conference Caribou’s IPO, described CB-
19

20 ²¹ Terry, Mark, *Despite One Patient Death, CRISPR Therapeutics’ Off-the-Shelf CAR-T Shows*
21 *Promise*, BIOSPACE, (Oct. 21, 2020) [https://www.biospace.com/article/crispr-therapeutics-car-t-](https://www.biospace.com/article/crispr-therapeutics-car-t-therapy-for-b-cell-cancers-encouraging-in-phase-i/)
22 [therapy-for-b-cell-cancers-encouraging-in-phase-i/](https://www.biospace.com/article/crispr-therapeutics-car-t-therapy-for-b-cell-cancers-encouraging-in-phase-i/) (“10/21/20 Biospace Article”) (“Joseph
23 McGuirk, professor of Medicine and division director of Hematologic Malignancies and Cellular
24 Therapeutics at the University of Kansas Medical Center and investigator in the Phase I CARBON
trial, noted, ‘From this early data read-out, CTX110 has shown dose-dependent efficacy and
response rates that are comparable to the early autologous CAR-T trials. Furthermore, CTX110
had an acceptable safety profile, which could make CAR-Ts more widely accessible.’”).

25 ²² Allogene Therapeutics, Inc., *Allogene Therapeutics Presents Positive Phase 1 Data on ALLO-*
26 *501 and ALLO-501A in Relapsed/Refractory Non-Hodgkin Lymphoma at the 2021 Annual*
27 *Meeting of the American Society of Clinical Oncology* (Jun. 4, 2021 9AM ET),
[https://ir.allogene.com/news-releases/news-release-details/allogene-therapeutics-presents-](https://ir.allogene.com/news-releases/news-release-details/allogene-therapeutics-presents-positive-phase-1-data-allo-501)
[positive-phase-1-data-allo-501](https://ir.allogene.com/news-releases/news-release-details/allogene-therapeutics-presents-positive-phase-1-data-allo-501) (“6/4/21 Allogene News”).

010 as being “*the first AlloCAR-T into the clinic with a PD-1 knockout*. And our reason for removing PD-1, using our genome editing technology is to prevent premature T-cell exhaustion to maintain these AlloCAR-Ts and a high anti-tumor activity state for a longer period of time, of course this is one approach for persistence.”²³

D. Unbeknownst to Investors, The Exchange Act Defendants Knew or Should Have Known that CB-010’s Treatment Effect Was Not as Durable or as Dose-Dependent as Caribou’s Preclinical Data Purportedly Indicated.

67. The Exchange Act Defendants misled investors regarding the durability assumptions for CB-010 which were based on Caribou’s preclinical data.

68. At the time of the IPO, the Exchange Act Defendants knew or should have known, but concealed from investors, what the Company’s mice data showed regarding overall tumor burden or cancer progression after Day 108 and survivability after day 160. Despite knowing that 6 months of data is the minimum necessary to demonstrate treatment durability, Defendants either concealed from investors mice data past 5.3 months or failed to continue to study mice past 5.3 months. In either case, the Exchange Act Defendants had no basis on which to assure investors that Caribou’s preclinical data signaled durability absent more robust and adequate disclosures.

69. In addition, two months prior to the IPO, a Phase 1 clinical trial sponsored by Gracell Biotechnologies Inc. (“Gracell”) concluded. Gracell is a Chinese company publicly traded on the NASDAQ which has “a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential to overcome major industry challenges that persist with conventional CAR-T therapies, including lengthy manufacturing time, suboptimal production quality, high therapy cost and lack of effective CAR-T therapies for solid tumors.”²⁴

70. Like Caribou’s CB-010 – which purportedly was the first ever allogeneic CAR-T therapy that knocked out PD-1 – the Gracell clinical trial tested a treatment that knocked out PD-

²³ Bloomberg Transcript, *Citi’s 16th Annual BioPharma Virtual Conference* (Sept. 9, 2021).

²⁴ Gracell Biotechnologies Inc., *Corporate Profile*, <https://ir.gracellbio.com/>.

1 1 in relapsed cancer patients (“Gracell Trial”). The Exchange Act Defendants were either aware
 2 of the Gracell Trial or recklessly failed to learn of it, given the similarity between the two
 3 treatments and the Company’s focus on its competitors.

4 71. The Gracell Trial only generated a response in 2 out of 15 patients. As the
 5 researchers explained, the “poor clinical response implies that CAR-T cell-intrinsic modification
 6 alone, for example, ***knocking out PD-1 in CAR-T cells, may not be enough to induce promising***
 7 ***outcomes in the treatment of patients.***”²⁵ The Exchange Act Defendants did not disclose the
 8 results of or the existence of the Gracell Trial in the Offering Documents.

9 72. The Exchange Act Individual Defendants repeatedly spoke about and touted CB-
 10 010’s preclinical and clinical trial data to the investing public throughout the Class Period, at a
 11 time when they already had results from that data. Specifically, for nearly two years, the
 12 Exchange Act Individual Defendants made numerous statements to investors boasting about CB-
 13 010’s preclinical and clinical trial data every quarter, specifically touting the purported durability
 14 of its treatment effect, when they knew or should have known the results from the Company’s
 15 own true preclinical data and the Gracell Trial – both of which undermined their durability
 16 statements. The fact that the Exchange Act Individual Defendants spoke so often and in such
 17 detail about the CB-010 data demonstrates that the data was critically important to them and that
 18 they had fully analyzed that data and were intimately familiar with all the preclinical and clinical
 19 trial results.

20 73. Additionally, when Caribou went public, analysts specifically compared it to its
 21 “peers Editas Medicine (EDIT), Intellia Therapeutics, and CRISPR Therapeutics (CRSP) who
 22 have already gone public, [and] now command a combined market capitalization of over \$25
 23 billion.”²⁶ Other “[m]ajor competitive vendors that provide or are developing related treatments
 24

25 _____
 26 ²⁵ Wang, Z., Li, N., Feng, K. et al. *Phase I study of CAR-T cells with PD-1 and TCR disruption*
 in mesothelin-positive solid tumors. *Cell Mol Immunol* 18, 2188-98 (2021) (“2021 Wang Study”).

27 ²⁶ 7/11/21 SA Article.

1 include: Beam Therapeutics, Metagenomi Technologies, Prime Medicine, Scribe Therapeutics,
 2 Allogene Therapeutics (ALLO), bluebird bio (BLUE), Cellectis ([CLLS](#)) ([OTCPK:CMVLF](#)),
 3 Precision BioSciences ([DTIL](#)).²⁷

4 74. The market also appeared to keep track of Caribou’s competitors and bought
 5 and/or sold Caribou stock in reaction to its competitors’ news. For example, the Company’s
 6 “stock [fell] considerably” after the FDA put a clinical hold on Allogene because the market
 7 likely thought “that even if the [gene editing] tool is different, the effect may be similar.” Indeed,
 8 Caribou’s “chRDNA technology accomplishe[d] exactly the same kind of multiple genomic edits
 9 which might have caused trouble for Allogene.”²⁸

10 75. After Caribou’s IPO, certain competitors whose clinical trials were ahead of its
 11 ANTLER Trial posted their positive results. On December 13, 2021, Allogene published updated
 12 data from two Phase 1 clinical trials of its lead anti-CD19 AlloCART T therapy programs which
 13 was “‘on par’ with autologous CAR T therapy”: no relapses in large B cell lymphoma (“LBCL”)
 14 CAR-T naïve patients across trials who had achieved a CR at six months and a 44% CR rate with
 15 ongoing CRs at nine months.²⁹

16 76. On June 6, 2022, Adicet announced updated data from its Phase 1 study of its
 17 CAR-T cell therapy for r/r B-NHL showing 75% CR rate across all dose levels and 50% of
 18 evaluable patients with at least six months follow-up remaining cancer-free, which indicated
 19 “durable anti-tumor responses with potential for dose related increase in durability.”³⁰

20 77. On June 8, 2022, Precision announced new clinical data for its CD19 CAR-T
 21

22 ²⁷ 7/22/21 SA Article.

23 ²⁸ 10/12/21 SA Article.

24 ²⁹ 6/4/21 Allogene News.

25 ³⁰ Adicet Bio, Inc., *Adicet Bio Reports Emerging Data from ADI-001 Phase 1 Trial at the*
 26 *American Society of Clinical Oncology Annual Meeting*, BUSINESSWIRE (Jun. 6, 2022 7AM ET),
 27 <https://www.businesswire.com/news/home/20220603005481/en/Adicet-Bio-Reports-Emerging-Data-from-ADI-001-Phase-1-Trial-at-the-American-Society-of-Clinical-Oncology-Annual-Meeting>.

1 therapy showing a 73% CR rate among evaluable relapsed patients and a 50% durable response
2 rate greater than six months.³¹

3 16. Caribou's Class Period representations portrayed its CB-010 clinical results as in-
4 line with, if not superior to, its competitors' results. For example, on May 12, 2022, the Company
5 released initial results from its Phase 1 trial showing 80% CR rate as of the February 23, 2022
6 data cutoff date and that patients with a CR at 28 days had maintained it at three months. That
7 same day, Haurwitz put these results in perspective, noting "that the approved CAR-Ts that focus
8 on CD19-positive disease have achieved overall response rates of about 50% to 70% and overall
9 response rates of 30% to 50%. These include Gilead's Yescarta, Bristol Myers Squibb's Breyanzi
10 and Novartis' Kymriah."³² Responding to these statements, Caribou's stock surged 27%.³³

11 **E. The Relevant Truth Emerges Over Two Corrective Disclosures.**

12 78. Before markets opened on June 10, 2022, Caribou issued a press release reporting
13 "[p]ositive" data from the ANTLER Phase 1 clinical trial. Among other results, the Company
14 reported that "[a]t 6 months following the single dose of CB-010, [only] 40% of patients
15 remained in CR (2 of 5 patients) as of the May 13, 2022 data cutoff date."³⁴ This stood in contrast
16 to the data Caribou reported just one month ago, one day shy of the May 13, 2022 data cutoff

17
18 ³¹ Precision Biosciences, Inc., *Precision Biosciences Provides Update on Allogeneic CAR T*
19 *Programs and Path Forward with Its Lead PBCAR00191 Candidate for CAR T Relapsed Patient*
20 *Population*, BUSINESSWIRE (Jun. 8, 2022), [https://investor.precisionbiosciences.com/news-](https://investor.precisionbiosciences.com/news-releases/news-release-details/precision-biosciences-provides-update-allogeneic-car-t-programs)
21 [releases/news-release-details/precision-biosciences-provides-update-allogeneic-car-t-programs](https://investor.precisionbiosciences.com/news-releases/news-release-details/precision-biosciences-provides-update-allogeneic-car-t-programs).

22 ³² Armstrong, Annalee, Caribou ready to uncork the chardonnay thanks to first-in-human CAR-
23 T results, FIERCE BIOTECH (May 12, 2022 10AM)
24 [https://www.fiercebiotech.com/biotech/caribou-ready-uncork-chardonnay-thanks-first-human-](https://www.fiercebiotech.com/biotech/caribou-ready-uncork-chardonnay-thanks-first-human-car-t-results)
25 [car-t-results](https://www.fiercebiotech.com/biotech/caribou-ready-uncork-chardonnay-thanks-first-human-car-t-results) ("5/12/22 Fierce Biotech Article").

26 ³³ Block, Jonathan, *Caribou Biosciences rises 27% on early-stage CAR-T therapy data*, SEEKING
27 ALPHA (5/12/2022 10:50AM ET), [https://seekingalpha.com/news/3837864-caribou-biosciences-](https://seekingalpha.com/news/3837864-caribou-biosciences-rises-27-on-early-stage-car-t-therapy-data-for-non-hodgkin-lymphoma)
28 [rises-27-on-early-stage-car-t-therapy-data-for-non-hodgkin-lymphoma](https://seekingalpha.com/news/3837864-caribou-biosciences-rises-27-on-early-stage-car-t-therapy-data-for-non-hodgkin-lymphoma).

29 ³⁴ Caribou Biosciences, Inc., *Caribou Biosciences Reports Positive Additional Data from CB-*
30 *010 Allogeneic CAR-T Cell Therapy Phase 1 ANTLER Trial at the European Hematology*
31 *Association (EHA) 2022 Hybrid Congress*, GLOBE NEWSWIRE (Jun. 10, 2022),
32 [https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-positive-additional-data-cb-010)
33 [positive-additional-data-cb-010](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-positive-additional-data-cb-010) ("June 2022 Press Release").

1 date, showing 80% CR at 3 months. The tapering off of CR after treatment with CB-10 prompted
 2 concern over the Company's ability to demonstrate CB-010's durability.

3 79. This news caused Caribou's stock price to fall \$3.62 per share, or 41.5%, on heavy
 4 trading to close at \$5.10 per share on June 13, 2022.

5 80. But when an analyst asked about "whether we expect efficacy to improve the
 6 higher doses," Haurwitz responded, "to be fair and maybe a bit tongue and cheek, it's pretty hard
 7 to beat 100% CR rate and I think what we're really focused on at this point is the durability of
 8 these responses. [S]o the snapshot of data that we have today is 40% of patients remaining in CR
 9 six months out, which we think is very promising initial data and obviously something we'll
 10 continue to track for patients at this dose level as well as in dose level two. That's really a big
 11 motivator for moving to 80 million cells for the second cohort."³⁵ As a result, investors still
 12 believed that there would be a dose-related increase in durability. Analysts too believed Caribou
 13 was "on the right track ... because it had seen excellent data from several patients that were only
 14 given one starting dose of CB-010 which is 40×10^6 CAR-T cells."³⁶

15 81. Haurwitz further specifically assured investors that "[t]he long-term durability at
 16 dose level 1 is comparable to autologous cell therapies," implying that higher dosing-related
 17 durability would be comparable as well. Analysts following Caribou reiterated this statement in
 18 recommending the stock: "it is already established that just at dose level 1 of CB-010, it is already
 19 on par with current autologous CAR-T therapies. That's impressive, considering data for dose
 20 level 2 and dose level 3 have not even been released yet."³⁷

21 82. But on July 13, 2023, Caribou was forced to report poor "long-term follow-up
 22 data from the dose escalation portion of the ongoing ANTLER Phase 1 trial," including that in

23
 24 ³⁵ Bloomberg Transcript, *CB-010 ANTLER Clinical Data at EHA 2022* (Jun. 10, 2022).

25 ³⁶ 8/1/22 SA Article.

26 ³⁷ Chrisomalis, Terry, *Caribou: Potential to Improve Response Duration With Higher Dose*
 27 *Level*, SEEKING ALPHA (Jan. 24, 2023 7:12AT ET), <https://seekingalpha.com/article/4571880-caribou-potential-to-improve-response-duration-with-higher-dose-level>.

three subjects given 120 million cells, there was one non responder (Caribou’s first) and two remissions lasting less than three months. Patients thus continued relapsing despite CB-010 being dosed higher, confirming the Company’s inability to demonstrate long-term durability.³⁸ In addition, for the first time, Caribou cautioned against accepting its Class Period statements comparing its results to its competitors at face value because it “has not performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-010, and Caribou has only reviewed publicly available reports of those trials. As such, the results of these other clinical trials may not be comparable to clinical results for CB-010.”³⁹

83. This news caused Caribou’s stock price to fall \$1.84 per share, or 22.6%, on heavy trading to close at \$6.30 per share on July 14, 2023.

V. THE EXCHANGE ACT DEFENDANTS’ FALSE AND MATERIALLY MISLEADING STATEMENTS AND OMISSIONS⁴⁰

A. False and Materially Misleading Statements in the Registration Statement

84. The Registration Statement contained untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading under the circumstances under which they were made.

85. In touting CB-010’s PD-1 knockout effect and the treatment’s attendant clinical prospects, the Registration Statement stated, *inter alia*:

We use Cas9 chRDNA guides to make three edits to manufacture CB-010. We introduce, with high efficiency and specificity, the gene encoding the CD19-specific CAR into the gene encoding the T cell receptor alpha constant, or TRAC, a component of the native T cell receptor, or TCR. This simultaneously integrates the CD19 CAR site-specifically into the T cell genome and eliminates TCR expression to reduce the risk of graft versus host disease, or GvHD. ***We also knock***

³⁸ Caribou Biosciences, Inc., *Caribou Biosciences Reports Positive Clinical Data from Dose Escalation of CB-010 ANTLE Phase 1 Trial in r/r B-NHL*, GLOBE NEWSWIRE (Jul. 13, 2023), (“7/13/23 Press Release”).

³⁹ Bloomberg Transcript, *CB-010 Clinical Program Update* (Jul. 13, 2023) (“7/13/23 Call”).

⁴⁰ The portions of the statements alleged to be false or misleading are in bold and italics in this section.

1 *out the gene encoding the PD-1 protein in these cells to boost the persistence of*
 2 *CAR-T cell antitumor activity. We believe that the PD-1 knockout has the*
 3 *potential to reduce the likelihood of rapid tumor recurrence and potentially*
 4 *confer a better therapeutic index compared to other allogeneic CAR-T cells. To*
 5 *our knowledge, CB-010 is the first allogeneic CAR-T cell therapy with a PD-1*
 6 *knockout in clinical studies* and it is being evaluated in our open-label, multicenter ANTLER phase 1 clinical trial in the United States in adults with relapsed or refractory B cell non-Hodgkin lymphoma (NCT04637763). We have dosed the first patient in this clinical trial. We expect to have initial data from this clinical trial in 2022.

7 86. The statements in ¶85 *supra* in bold and italics were false and materially
 8 misleading and/or omitted to state material facts necessary to make them not misleading when
 9 made because the Exchange Act Defendants failed to disclose: (i) the existence of the Gracell
 10 Trial, which meant that Caribou was not the first to use the PD-1 knockout in an allogeneic CAR-
 11 T cell treatment; and (ii) that the Gracell Trial had already demonstrated that knocking out the
 12 PD-1 protein was not linked to enhanced durability or clinical performance, calling into question
 13 the purportedly unique advantage of CB-010 as a treatment.

14 87. In the Registration Statement, the Exchange Act Defendants also touted PD-1
 15 knockout as a solution to the problem that allogeneic treatments have had with persistence, due
 16 to the human immune system attacking the foreign donor cells:

17 Our first lead product candidate, CB-010, is, to our knowledge, the first clinical-
 18 stage allogeneic anti-CD19 CAR-T cell therapy with PD-1 removed from the
 19 CAR-T cell surface by a genome-edited knockout of the PDCD1 gene. *We have*
 20 *demonstrated in preclinical models that the PD-1 knockout improves the*
 21 *persistence of antitumor activity by disrupting a pathway that leads to rapid T*
 22 *cell exhaustion.* We have dosed the first patient in our ANTLER phase 1 clinical
 23 trial for CB-010, a study in patients with relapsed or refractory B cell non-Hodgkin
 24 lymphoma, with initial data expected in 2022.

25 88. The statement identified in ¶87, *supra*, in bold and italics was false and materially
 26 misleading and/or omitted to state material facts necessary to make it not misleading when made
 27 because Caribou then lacked the clinical data to show that the PD-1 knockout would improve
 allogeneic durability given that the pre-clinical data in the Registration Statement did not go past
 5.3 months and given that 6 months is the minimum threshold for durability.

89. In the Registration Statement, the Exchange Act Defendants claimed Caribou had

a competitive edge over other companies developing allogeneic therapies:

The genome-editing technologies currently used in the allogeneic cell therapy field generally have limited efficiency, specificity, and versatility for performing the multiple, precise genomic edits necessary to address insufficient persistence. Our chRDNA technology is designed to address these genome-editing limitations and improve cell therapy activity. By applying this approach to allogeneic cell therapies, we believe we can unlock their full potential by improving upon their effectiveness and durability.

90. The statements in ¶89, *supra*, in bold and italics were false and materially misleading and/or omitted to state material facts necessary to make them not misleading when made because the Exchange Act Defendants failed to disclose that Caribou's competitors in the allogeneic gene-editing space, including Allogene and CRISPR, had already published data that showed comparable or better durability data than approved autologous therapies, and Caribou lacked data to show that its technology was superior.

91. In the Registration Statement, the Exchange Act Defendants also touted the Company's preclinical data from a study performed in mice, presenting data for 160 days of study in which mice were given either a control injection, CB-010 without PD-1 knockout, or CB-010 with the PD-1 knockout. The Registration Statement stated the following with respect to CB-010's clinical prospects based on the mice study:

In our preclinical studies, we demonstrated that the removal of the PD-1 checkpoint from the CB-010 CAR-T cells provided a statistically significant survival advantage in mice bearing robust and metastatic B cell tumors.

Overall, our data demonstrate that the removal of the PD-1 checkpoint from the CB-010 CAR-T cells provided a statistically significant survival advantage in mice bearing robust and metastatic B cell tumors. Our data suggest that the PD-1 knockout may have led to a more robust debulking of the tumor by CB-010 during the early part of the study compared to the conventional allogeneic CD19 CAR-T cells, leading to a reduction in the recurrence of the tumor cells. Based on these data, we believe CB-010 has the potential for a better therapeutic index compared to other allogeneic CAR-T cells. If a lower dose of CB-010 has meaningful activity in the clinical setting, it would lead to several potential advantages including limited toxicity, increased numbers of doses per manufacturing run, and a reduced cost of goods.

92. The statements in ¶91, *supra*, in bold and italics were false and materially misleading and/or omitted to state material facts necessary to make them not misleading when made because the Exchange Act Defendants omitted to disclose: (i) the existence of the Gracell Trial and the uncertainty about the clinical benefits of removing PD-1 checkpoints, as the Gracell Trial already demonstrated; and (ii) given that 6 months is the minimum threshold for durability, relying on 5.3 months of mice data would not be an indication of CB-010's durability in the ANTLER trial.

93. With respect to the purported durability of CB-010's treatment effect, as afforded by the PD-1 knockout strategy, the Registration Statement stated, in relevant part:

One of the approaches we deploy to increase the persistence of CAR-T cell antitumor activity is to remove PD-1 from the CAR-T cell surface We believe that knocking out PD-1 will maintain the CAR-T cells in a higher antitumor state for a longer period of time, and we believe this will result in greater initial tumor debulking in the patient which will lead to long-term durability of CAR-T cell antitumor activity *[O]ur preclinical in vivo data from experiments conducted in mouse xenograft models submitted as part of our CB-010 IND [Investigational New Drug Application] demonstrate that knocking out PD-1 leads to a significant increase in the durability of antitumor activity and therefore overall mouse survival.* To our knowledge, our lead product candidate [CB-010] is the first allogeneic CAR-T cell therapy in a clinical study with a PD-1 knockout, and we believe will drive the durability of allogeneic CAR-T cell antitumor activity.

94. The statement in ¶93, *supra*, in bold and italics was false and materially misleading and/or omitted to state material facts necessary to make it not misleading when made for the reasons set forth in ¶88, *supra*.

B. The Exchange Act Defendants Violated The Disclosure Obligations of Items 303 and 105 of Regulation S-K

95. SEC Regulation S-K required the Exchange Act Defendants to describe in the Registration Statement, "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material impact ... on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii) ("Item 303") (2017). "Disclosure is mandatory where there is a known trend or uncertainty that is reasonably likely to have a material effect on the registrant's financial condition or results of operations." SEC Release Nos. 33-8056;

1 34-45321; FR-61.

2 96. The SEC has emphasized that Item 303's disclosure requirements are "intended
3 to give the investor an opportunity to look at the company through the eyes of management by
4 providing both a short and long-term analysis of the business of the company" and "a historical
5 and prospective analysis of the registrant's financial condition ... with particular emphasis on the
6 registrant's prospects for the future." S.E.C. Release No. 6835, 1989 WL 1092885, at *3, *17.
7 Thus, "material forward-looking information regarding known material trends and uncertainties
8 is required to be disclosed as part of the required discussion of those matters and the analysis of
9 their effects." *See* Comm'n Guidance Regarding Mgmt.'s Discussion and Analysis of Fin.
10 Condition and Results of Operations, S.E.C. Release No. 8350, 2003 WL 22996757, at *11 (Dec.
11 19, 2003).

12 97. Item 303 affirmatively required the Exchange Act Defendants to disclose the
13 trends and uncertainties related to Caribou with a high degree of specificity to comply with
14 Regulation S-K's rigorous disclosure requirements. Yet the Exchange Act Defendants omitted
15 to disclose in the Registration Statement that at least two competitors had already demonstrated
16 that their allogeneic CAR-T cell therapy had dose-dependent efficacy and response rates
17 comparable to the early autologous CAR-T trials, so Caribou was not the first. And the Exchange
18 Act Defendants also concealed that a Phase 1 clinical trial in which PD-1 was knocked out in
19 relapsed cancer patients had previously only generated a response in 2 out of 15 patients, leading
20 the researchers leading that trial to conclude "that CAR-T cell-intrinsic modification alone, for
21 example, knocking out PD-1 in CAR-T cells, may not be enough to induce promising outcomes
22 in the treatment of patients." Accordingly, it was misleading for Caribou to present its preclinical
23 data as having "demonstrated" the durability of its allogeneic treatment effect any more or better
24 than its competitors' preclinical data had. The Exchange Act Defendants' omissions thus
25 concealed from investors an uncertainty about the commercial viability of the Company's CB-
26 010 therapy, and of the Company itself because its therapies all hinged on the same technology.

1 98. The Exchange Act Defendants’ material omissions also violated their affirmative
 2 disclosure duties imposed by Regulation S-K Item 105, which required them to include in the
 3 Registration Statement a “discussion of the most significant factors that make the offering
 4 speculative or risky.” 17 C.F.R. § 229.503I (2011). Item 105’s purpose is “to provide investors
 5 with a clear and concise summary of the material risks to an investment in the issuer’s securities.”
 6 Sec. Offering Reform, S.E.C. Release No. 8501, 2004 WL 2610458, at *86 (Nov. 3, 2004). The
 7 discussion of risk factors must be specific to the particular company and its operations, and must
 8 explain how the risk affects the company and/or the securities being offered. Generic or
 9 boilerplate attempts to disclose potential risks and shield oneself from liability do not tell
 10 investors how the specific risks could affect their investment. *See* Statement of the Comm’n
 11 Regarding Disclosure of Year 2000 Issues and Consequences by Pub. Cos., Inv. Advisers, Inv.
 12 Cos., & Mun. Sec. Issuers, 1998 WL 425894, at *14 (Jul. 29, 1998).

13 99. Item 105 required the Exchange Act Defendants to disclose the most significant
 14 risks that could adversely affect Caribou’s present or future business expectations and not just
 15 reiterate boilerplate, generic risks that could apply to virtually any other drug development or
 16 biopharmaceutical company.

17 100. The risk that CB-010 therapy would not prove durable in humans, given that
 18 knocking out the PD-1 in CAR-T cells had already shown to not be a promising outcome when
 19 used to treat humans, was already likely to occur, and was likely to adversely affect the Caribou’s
 20 present or future business expectations, and, in fact, did have a negative impact on its business
 21 prospects, yet the Exchange Act Defendants failed to disclose these specific risks in the
 22 Registration Statement.

23 **C. After the IPO, the Exchange Act Defendants Continued to Mislead Investors**
 24 **Concerning CB-010**

25 101. On September 2, 2021, Caribou filed its quarterly report on Form 10-Q with the
 26 SEC, reporting its financial and operational results for the quarter ended June 30, 2021. With
 27 respect to the purported novelty of CB-010 and the durability of its treatment effect, that filing

1 stated, in relevant part, that:

2 ***Our lead product candidate, CB-010, is, to our knowledge, the first clinical-stage***
 3 ***allogeneic anti-CD19 CAR-T cell therapy with programmed cell death protein 1***
 4 ***(“PD-1”) removed from the CAR-T cell surface by a genome-edited knockout of***
 5 ***the PDCD1 gene. We have demonstrated in preclinical models that the PD-1***
 6 ***knockout improves the persistence of antitumor activity*** by disrupting a pathway
 7 that leads to rapid T cell exhaustion.⁴¹

8 102. The statements in ¶101, *supra*, in bold and italics were false and materially
 9 misleading when made and/or omitted material facts necessary to make them not misleading when
 10 made because: (i) Caribou was not the first to use the PD-1 knockout in an allogeneic CAR-T cell
 11 treatment; (ii) the Gracell Trial had already demonstrated that knocking out the PD-1 protein was
 12 not linked to enhanced durability or performance; and (iii) Caribou then lacked sufficient
 13 preclinical data to conclude that the PD-1 knockout improved the persistence of anti-tumor
 14 activity because its pre-clinical data did not go beyond 5.3 months, below the minimum threshold
 15 for durability.

16 103. On November 9, 2021, Caribou filed its quarterly report on Form 10-Q with the
 17 SEC, reporting its financial and operational results for the quarter ended September 30, 2021.
 18 That filing contained substantively the same statements as referenced in ¶101, *supra*, regarding
 19 CB-010 being the “***first*** clinical-stage allogeneic anti-CD19 CAR-T cell therapy” with PD-1
 20 knocked out and Caribou’s “***demonstrat[ion] in preclinical models***” of CB-010’s resulting ability
 21 to “***improve[] the persistence of antitumor activity***.”⁴²

22 104. The statements in ¶103, *supra*, in bold and italics were false and materially
 23 misleading when made and/or omitted material facts necessary to make them not misleading
 24 because: (i) Caribou was not the first to use the PD-1 knockout in an allogeneic CAR-T cell
 25 treatment; (ii) the Gracell Trial had already demonstrated that knocking out the PD-1 protein was

26 ⁴¹ Caribou Biosciences, Inc., Form 10-Q for the quarter ending June 30, 2021 (Sept. 2, 2021),
 27 <https://investor.cariboubio.com/node/6856/html> (“2Q21 10-Q”).

⁴² Caribou Biosciences, Inc., Form 10-Q for the quarter ending September 30, 2021 (Nov. 9,
 2021), <https://investor.cariboubio.com/node/6986/html>.

not linked to enhanced durability or performance; and (iii) Caribou then lacked sufficient preclinical data to conclude that the PD-1 knockout improved the persistence of anti-tumor activity because its pre-clinical data did not go beyond 5.3 months, below the minimum threshold for durability.

105. On March 21, 2022, Caribou filed its 2021 10-K. That filing contained substantively the same statements as referenced in ¶101, *supra*, regarding CB-010 being the “***first*** clinical-stage allogeneic anti-CD19 CAR-T cell therapy” with PD-1 knocked out and Caribou’s “***demonstration in preclinical models***” of CB-010’s resulting ability to “***improve the persistence of antitumor activity***” which were false and materially misleading for the reasons set forth in ¶102, *supra*.

106. The 2021 10-K further stated that “our preclinical *in vivo* data from experiments conducted in mouse xenograft models submitted as part of our CB-010 IND application ***demonstrate that knocking out PD-1 leads to a significant increase in the durability of antitumor activity*** and therefore overall mouse survival.”

107. In addition, the 2021 10-K noted that the Company’s *in vitro* studies showed that “CB-010 cells demonstrate ***dose-dependent*** and robust cytotoxic activity at a range of effector-to-target ratios compared to negative control cells.”

108. The statements in ¶¶105-07, *supra*, in bold and italics were false and materially misleading when made and/or omitted material facts necessary to make them not misleading because: (i) Caribou lacked sufficient preclinical data to conclude that the PD-1 knockout improved the persistence of anti-tumor activity because its pre-clinical data did not go beyond 5.3 months, below the minimum threshold for durability and (ii) the Exchange Act Defendants had no reasonable basis to state that CB-010 demonstrated dose dependency; indeed, as investors would later learn, patients did not exhibit durable responses to CB-010 despite being given triple the initial dose.

109. On May 9, 2022, Caribou filed its quarterly report on Form 10-Q with the SEC,

1 reporting its financial and operational results for the quarter ended March 31, 2022. That filing
 2 contained substantively the same statements as referenced in ¶101, *supra*, regarding CB-010
 3 being the “**first** clinical-stage allogeneic anti-CD19 CAR-T cell therapy” with PD-1 knocked out
 4 and Caribou’s “**demonstrat[ion] in preclinical models**” of CB-010’s resulting ability to
 5 “**improve[] the persistence of antitumor activity**”⁴³ which were false and materially misleading
 6 for the same reasons stated in ¶102, *supra*.

7 110. Then, on May 12, 2022, Caribou issued a press release announcing “Positive Initial
 8 Data for CB-010 Anti-CD19 Allogeneic CAR-T Cell Therapy.”⁴⁴ That data included:

9 -- **100% ORR (5 of 5 patients) and 80% CR (4 of 5 patients) achieved following**
 10 **1 dose at the initial dose level in patients with aggressive r/r B-NHL –**

11 -- **CB-010 is the 1st allogeneic CAR-T cell therapy to achieve 100% ORR (5 of 5**
 12 **patients)– --**

13 111. The May 2022 Press Release specifically stated that “[a]s of the February 23, 2022
 14 data cutoff date, 6 patients had been treated with CB-010 and 5 had completed the 28-day dose
 15 limiting toxicity evaluation period. 100% (n=5) achieved a response; 80% (n=4) achieved a CR,
 16 and 20% (n=1) achieved a partial response (PR). All 4 patients who achieved a CR at 28 days had
 17 an ongoing CR at 3 months.” Accordingly, the Company’s “**initial results demonstrate[d] a**
 18 **100% overall response rate (ORR) and 80% complete response rate (CR)** in cohort 1 (n=5
 19 evaluable) from its ANTLER Phase 1 trial for CB-010 in patients with relapsed or refractory B
 20 cell non-Hodgkin lymphoma (r/r B-NHL).”

21 112. In addition, the May 2022 Press Release quoted Haurwitz as touting that “[t]hese
 22 excellent initial outcomes represent important steps toward **validating our chRDNA genome-**
 23 **editing platform as well as our plans for future development of CB-010 and our broader**

24 ⁴³ Caribou Biosciences, Inc., Form 10-Q for the quarter ending March 31, 2022 (May 9, 2022),
 25 <https://investor.cariboubio.com/node/7346/html>.

26 ⁴⁴ Caribou Biosciences, Inc., *Caribou Biosciences Announces Positive Initial Data for CB-010*
 27 *Anti-CD19 Allogeneic CAR-T Cell Therapy*, GLOBE NEWSWIRE (MAY 12, 2022),
<https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-positive-initial-data-cb-010-anti> (“May 2022 Press Release”).

1 *pipeline*” and CB-010 as “the *first* allogeneic anti-CD19 CAR-T cell therapy in the clinic with a
 2 PD-1 knock-out, a genome-editing strategy designed to limit premature CAR-T cell
 3 exhaustion...”

4 113. Also on May 12, 2022, Fierce Biotech provided a statement from Haurwitz
 5 comparing these results to approved autologous therapies: “the approved CAR-Ts that focus on
 6 CD19-positive disease have achieved overall response rates of about 50% to 70% and overall
 7 response rates of 30% to 50%. These include Gilead’s Yescarta, Bristol Myers Squibb’s Breyanzi
 8 and Novartis’ Kymriah.”⁴⁵

9 114. These statements caused Caribou stock to surge 27%. However, when the
 10 Exchange Act Defendants released this early data, they had in hand the ANTLEER six-month data,
 11 which they promised they would present the following month at the European Hematology
 12 Association (“EHA”) Conference. Indeed, the cutoff date for the ANTLEER six-month data was
 13 May 13, 2022, just one day after the Exchange Act Defendants issued the May 2022 Press
 14 Release. As discussed herein, results from the six-month data were far less impressive,
 15 demonstrating that by six months – the minimum threshold for treatment durability – three of six
 16 patients in the ANTLEER trial relapsed with progressive disease and only two out of five patients
 17 were still responding to treatment at six months. The statements in the May 2022 Press Release
 18 were misleading for failing to disclose the six-month data of which the Exchange Act Defendants
 19 were then in possession and which demonstrated that CB-010 lacked durability.

20 115. On June 10, 2022 the Company presented six-month data for the CB-010
 21 ANTLEER Trial at the EHA Conference. The data demonstrated that by six months, three of the
 22 six patients in ANTLEER had relapsed with progressive disease. Despite this, the Exchange Act
 23 Defendants continued to assure investors that CB-010 leads to longer durability because of its
 24 unique PD-1 knockout design, and to tout Caribou’s preclinical study results.

25 116. During the EHA conference call and webcast (“June 2022 Conference Call”),
 26

27 ⁴⁵ 5/12/22 Fierce Biotech Article.

1 Steven Kanner, Caribou's Chief Scientific Officer stated that "*on the poster in a preclinical*
 2 *model where we allowed the mice to become heavily burdened by tumor growth for quite some*
 3 *time and then we did the treatments and what you see is that CB-010 leads to longer durability*
 4 than an identical cell without the PD-1 knockout..."

5 117. In addition, in response to a question from analyst Luca Rissi, Haurwitz
 6 specifically stated that regarding:

7 whether we expect efficacy to improve the higher doses[,] to be fair and maybe a
 8 bit tongue and cheek, it's pretty hard to beat 100% CR rate and I think what we're
 9 really focused on at this point is the durability of these responses. To *the snapshot*
 10 *of data that we have today is 40% of patients remaining in CR six months out,*
 11 *which we think is very promising initial data* and obviously something we'll
 continue to track for patients at this dose level as well as in dose level two. *That's*
really a big motivator for moving to 80 million cells for the second cohort.

12 118. Kanner and Haurwitz's statements in ¶¶116-17, *supra*, in bold and italics were
 13 false and materially misleading when made and/or failed to disclose the Gracell Trial which
 14 seriously called into question the PD-1 knockout mechanism as a basis for longer durability and
 15 thus whether increased dosing would lead to better durability.

16 119. Then, on August 9, 2022, Caribou filed its quarterly report on Form 10-Q with the
 17 SEC, reporting its financial and operational results for the quarter ended June 30, 2022. In that
 18 filing, the Exchange Act Defendants continued to tout Caribou's "*demonstrat[ion] in preclinical*
 19 *models*" of CB-010's purported ability to "*improve[] the persistence of antitumor activity.*"⁴⁶

20 120. The statement in ¶119, *supra*, in bold and italics was false and materially
 21 misleading and/or omitted material facts necessary to make it not misleading because Caribou
 22 lacked sufficient preclinical data to conclude that the PD-1 knockout improved the persistence of
 23 anti-tumor activity. Specifically, the pre-clinical data did not go beyond 5.3 months, below the
 24 minimum threshold for durability.

25
 26
 27 ⁴⁶ Caribou Biosciences, Inc., Form 10-Q for the quarter ending June 30, 2022 (Aug. 9, 2022),
<https://investor.cariboubio.com/node/7496/html>.

1 121. On November 8, 2022, Caribou issued a press release reporting third quarter 2022
 2 financial results and providing a business update. That press release quoted Haurwitz, who stated,
 3 in relevant part:

4 *We have seen highly promising results from our lead allogeneic cell therapy,*
 5 *CB-010, at the lowest starting dose* in the ANTLER clinical trial in patients with
 6 [r/r -NHL] *The . . . antitumor activity for CB-010 at dose level 1 are*
 7 *encouraging*, and we look forward to generating additional efficacy and durability
 8 data from the dose escalation phase of the ANTLER trial.⁴⁷

9 122. Haurwitz’s statements in ¶121, *supra*, were false and materially misleading when
 10 made because she led investors to believe that increasing the dosage of CB-010 would lead to
 11 greater efficacy and durability. In truth, as Haurwitz was or should have been aware, the Gracell
 12 Trial called into question the viability of CB-010’s purportedly unique mechanism of action in
 13 knocking out PD-1, which meant that no matter how high the dose, CB-010 would not
 14 demonstrate efficacy and durability.

15 123. Also on November 8, 2022, Caribou filed its quarterly report on Form 10-Q with
 16 the SEC, reporting its financial and operational results for the quarter ended September 30, 2022.
 17 That filing contained substantively the same statements as referenced in ¶101, *supra*, regarding
 18 Caribou’s “*demonstrat[ion] in preclinical models*” of CB-010’s purported ability to “*improve[]*
 19 *the persistence of antitumor activity*,”⁴⁸ which were false and misleading for the reasons stated
 20 in ¶102, *supra*.

21 124. The Exchange Act Defendants also continued to mislead investors into believing
 22 that CB-010 was just as durable as autologous cell therapies. On November 17, 2022, during the
 23 Jefferies LLC London Healthcare Conference, Haurwitz stated that:

24 Quite remarkably, we saw a 100% complete response rate as best response, which

25 ⁴⁷ Caribou Biosciences, Inc., *Caribou Biosciences Reports Third Quarter 2022 Financial*
 26 *Results and Provides Business Update*, GLOBE NEWSWIRE (NOV. 8, 2022),
 27 [https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-third-quarter-2022-financial-results)
 [third-quarter-2022-financial-results](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-third-quarter-2022-financial-results) (“3Q22 Press Release”).

⁴⁸ Caribou Biosciences, Inc., Form 10-Q for the quarter ending September 30, 2022 (Nov. 8,
 2022), <https://investor.cariboubio.com/node/7661/html>.

1 to the best of my knowledge is the best anyone has seen for a cell therapy at such
 2 a low dose. And importantly, we've now observed a 50% six-month CR rate,
 3 showing really quite promising and durable activity. *To put this in context, what*
 4 *we often hear from KOLs in this space, is that there are real world experience*
with their patients in the clinic today, is about a 33% six months CR rate with
autologous CAR-Ts. So we think this is a really compelling start, especially
 considering that it's only just level 1.

5 125. Then, on December 7, 2022, during the Bank of America 2022 Biotech SMID Cap
 6 Conference, in response to a question from Senior Biopharma Analyst Jeff Beacham, Haurwitz
 7 similarly stated that:

8 To your point, clearly duration of response is really important in this field. And
 9 often *what we hear from physicians today whose patients are getting the*
 10 *approved commercial antillogous [ph] CAR-T products they're seeing something*
 11 *like 30 to 35% six months CR rates in the real world clinic experience.* And so,
 we were really pleased a little bit later this year to share a 50% six month CR rate
 for this initial cohort of patients.

12 126. And on December 12, 2022, Caribou issued a press release reporting 12-month
 13 clinical data from cohort 1 in the ANTLEER trial where patients were still given the initial 40x60
 14 CAR-T cell dose ("December 2022 Press Release"). While only 2 of 6 patients continued
 15 responding to treatment at 12-months, Haurwitz nevertheless represented that, "[t]he long-term
 16 *durability at dose level 1 is comparable to autologous cell therapies* and we believe CB-010 has
 17 the potential to set a new therapeutic bar for what allogeneic anti-CD19 CAR-T cell therapies can
 18 achieve."⁴⁹

19 127. Then, on March 9, 2023, Caribou issued a press release reporting fourth quarter
 20 and full year 2022 financial results and providing a business update.⁵⁰ That press release quoted
 21 Haurwitz as stating, in relevant part, "[t]he initial dose level of CB-010 demonstrated 6-month
 22

23 ⁴⁹ Caribou Biosciences, Inc., *Caribou Biosciences Reports CB-010 ANTLEER Phase 1 Trial*
 24 *Progress*, GLOBE NEWSWIRE (Dec. 12, 2022), [https://investor.cariboubio.com/news-](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-cb-010-antler-phase-1-trial-progress)
[releases/news-release-details/caribou-biosciences-reports-cb-010-antler-phase-1-trial-progress](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-cb-010-antler-phase-1-trial-progress).

25 ⁵⁰ Caribou Biosciences, Inc., *Caribou Biosciences Reports Fourth Quarter and Full Year 2022*
 26 *Financial Results and Provides Business Update*, GLOBE NEWSWIRE (Mar. 9, 2023),
 27 [https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-fourth-quarter-and-full-year-2022)
[fourth-quarter-and-full-year-2022](https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-fourth-quarter-and-full-year-2022) ("4Q22 Press Release").

1 *complete response rates that have the potential to rival the responses seen with approved*
 2 *autologous CAR-T cell therapies.”*

3 128. Haurwitz’s statements in ¶¶124-27, *supra*, were false and materially misleading
 4 when made for failing to disclose that unlike its autologous counterparts, CB-010 would not
 5 demonstrate increased durability when administered at a higher dose because the Gracell Trial
 6 seriously called into question CB-010’s PD-1 knockout as a basis for increased durability. At the
 7 very least, the Exchange Act Defendants were required to disclose the Gracell Trial and its
 8 implications to make the above statement not materially misleading.

9 129. Also on March 9, 2023, Caribou filed its annual report on Form 10-K with the
 10 SEC, reporting its financial and operational results for the quarter and year ended December 31,
 11 2022. That filing contained substantially the same statements referenced in ¶101, *supra*, regarding
 12 Caribou’s “*demonstrat[ion] in preclinical models*” of CB-010’s purported ability to “*improve[]*
 13 *the persistence of antitumor activity*,” which were false and materially misleading for the reasons
 14 stated in ¶102, *supra*.⁵¹

15 130. On May 9, 2023, Caribou filed its quarterly report on Form 10-Q with the SEC,
 16 reporting its financial and operational results for the quarter ended March 31, 2023. With respect
 17 to the purported durability of CB-010’s treatment effect, that filing stated, in relevant part, that
 18 “*We have demonstrated in preclinical models that the PD-1 knockout improves the durability*
 19 *of antitumor activity* by disrupting a pathway that leads to rapid T cell exhaustion.”⁵²

20 131. The statement in ¶130, *supra*, in bold and italics was false and materially
 21 misleading and/or omitted to state material facts necessary to make it not misleading when made
 22 because: (i) Caribou then lacked the pre-clinical data to show that PD-1 knockout would improve
 23 allogeneic durability given that the pre-clinical data in the Registration Statement did not go past
 24

25 ⁵¹ Caribou Biosciences, Inc., Form 10-K for the fiscal year ending December 31, 2022 (Mar. 9,
 26 2023), <https://investor.cariboubio.com/node/7886/html>.

27 ⁵² Caribou Biosciences, Inc., Form 10-Q for the quarter ending March 31, 2023 (May 9, 2023),
<https://investor.cariboubio.com/node/8011/html>).

5.3 months and given that 6 months is the minimum threshold for durability and (ii) the Exchange Act Defendants failed to disclose that the Gracell Trial seriously called into question the notion that the PD-1 knockout improves durability.

D. The Individual Exchange Act Defendants' False SOX Certifications

132. Appended as exhibits to each of Caribou's Class Period quarterly and annual reports on Forms 10-Q and 10-K filed with the SEC were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Exchange Act Individual Defendants certified that "[t]he [10-Q/10-K] fully complies with the requirements of section 13(a) or 15(d) of the [Exchange Act]" and that "[t]he information contained in the [10-Q/10-K] fairly presents, in all material respects, the financial condition and result of operations of the Company."

133. The Exchange Act Individual Defendants' Class Period SOX certifications were false and misleading because Caribou's Class Period 10-Q's and 10-K's did not fairly present in all material respects the financial condition and result of operations of the Company due to the false and materially misleading statements therein, as set forth above.

VI. LOSS CAUSATION

134. On June 10, 2022, during pre-market hours, Caribou issued a press release reporting "Positive Additional Data from CB-010 Allogeneic CAR-T Cell Therapy Phase 1 ANTLER Trial at the [EHA] 2022 Hybrid Congress,"⁵³ Among other results, that press release reported that "[a]t 6 months following the single dose of CB-010, **40% of patients remained in CR (2 of 5 patients) as of the May 13, 2022 data cutoff date.**"

135. And Jacob Plieth of Evaluate Vantage pointed out later that day:⁵⁴

Caribou has hailed its Crispr-edited CD19-targeting lead project, CB-010, as the first ever off-the-shelf Car-T to show a 100% complete response rate. **Unfortunately, this does not tell the whole story: as the group's EHA poster**

⁵³ 6/10/22 Press Release.

⁵⁴ Plieth, Jacob, *EHA 2022 - Caribou's turn to run into allo Car-T relapses*, EVALUATE VANTAGE (Jun. 10, 2022), <https://www.evaluate.com/vantage/articles/events/conferences/eha-2022-caribous-turn-run-allo-car-t-relapses> ("6/10/22 EV Article").

revealed today, few of the remissions are durable.

Caribou thus appears to be the latest allogeneic Car-T player to run into the problem of relapse, after this issue last year derailed Allogene, Crispr Therapeutics and Precision Biosciences.

* * *

[B]y six months three of the six patients relapsed with progressive disease. Two of the three remaining CRs were ongoing beyond six months, and Caribou added that the first patient treated remained in CR at their 12-month scan, after the abstract's cutoff date. All six subjects received the first dose level of 40 million cells, but it will not go unnoticed that the most durable CR is in follicular lymphoma, a relatively slow-growing disease.

136. This observed tapering-off of CR after treatment with CB-010 understandably prompted investor concern over Caribou's ability to demonstrate the durability of the CB-010 treatment. For example, also on June 10, 2022, online investor news resource *Seeking Alpha* reported that "Caribou [was] in selloff after [the] data for cancer candidate [CB-010]" because "only two patients . . . remained on CR as of the May [13, 2022] data cutoff."⁵⁵ Similarly, a Bloomberg Intelligence analyst wrote that CB-010 "showed lower-than-desired durability, with a [CR] in two out of five patients at six months[;]" and an SVB Securities analyst wrote that the update "has bears [i.e., pessimistic investors] arguing questions of durability of CR's among patients with the most aggressive disease[.]"

137. On this news, Caribou's stock price fell \$3.62 per share, or 41.51%, to close at \$5.10 per share on June 13, 2022 on heavy trading volume, damaging investors. Despite this decline in the Company's stock price, Caribou securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of the Exchange Act Defendants' continued misstatements and omissions regarding what the Company's clinical trials had demonstrated regarding the durability of CB-010's treatment effect.

138. Based on the Exchange Act Defendants' statements, analysts like RBC Capital Markets held onto the hope that increasing the dosage of CB-010 would yield durable responses.

⁵⁵ Lokuwithana, Dulan, *Caribou in selloff after data for cancer candidate; SVB says buy the dip*, SEEKING ALPHA (Jun. 10, 2022 2:36PM ET), <https://seekingalpha.com/news/3847775-crbus-stock-defended-at-svb-after-data-for-cancer-drugcrbu> ("6/10/22 SA Article")

On December 12, 2022, RBC Capital analysts wrote “[e]arly days and small n, but durability remains on par with auto-CART, and we argue the bear thesis that responses are short-lived and driven by high-dose lymphodepletion is losing traction. Importantly, safety remains clean, with no DLTs at the mid-dose and the study now proceeding to the high dose.”

139. Finally, on July 13, 2023, Caribou reported “long-term follow-up data from the dose escalation portion of the ongoing ANTLER Phase 1 trial,” including that in three subjects given 120 million cells, there was one non responder (Caribou’s first) and two remissions lasting less than three months. Patients thus continued relapsing despite CB-010 being dosed higher, confirming the Company’s inability to demonstrate long-term durability.⁵⁶ In addition, for the first time, Caribou cautioned against accepting its Class Period statements comparing its results to its competitors at face value because it “has not performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-010, and Caribou has only reviewed publicly available reports of those trials. As such, the results of these other clinical trials may not be comparable to clinical results for CB-010.”⁵⁷

140. As Plieth of Evaluate Vantage pointed out later that day:⁵⁸

With allogeneic Car-T projects struggling to yield lasting responses, six-month durability has emerged as something of a minimum for a patient’s remission to hit to be considered real. And yesterday Caribou joined Allogene in claiming that around half of lymphoma subjects treated with its project can develop responses that are maintained to this time point.

The 50% bar is relevant because it broadly matches what autologous Car-T therapies are capable of in this setting, and with the convenience of an off-the-shelf therapy the possible advantages are obvious. However, Caribou’s data, from the latest iteration of the Antler study of CB-010, make it clear that relapses will continue to be watched closely.

* * *

More puzzling is the fact that patients continue relapsing in spite of CB-010 being dosed higher. Four of the five new responders had been given 80 million cells, but in three subjects given 120 million cells there was one non-responder –

⁵⁶ 7/13/23 Press Release.

⁵⁷ 7/13/23 Call

⁵⁸ 7/14/23 EV Article.

Caribou's first – and two remissions lasting less than three months.

141. On this news, Caribou's stock price fell \$1.84 per share, or 22.6%, on heavy trading to close at \$6.30 per share on July 14, 2023, further damaging investors. Concerns that Caribou would not be able to demonstrate that the CB-010 treatment was durable even at higher doses thus were confirmed, despite repeated assurances by Defendants to the contrary. As *Seeking Alpha* reported that same day, the Company was “down 23% in Friday trading after announcing following Thursday's closing bell ... phase 1 data on a non-Hodgkin's lymphoma CAR-T candidate[,]” and “[o]ne peculiarity in the data, pointed out by Evaluate Vantage's Jacob Plieth, was that some patients are still relapsing despite receiving a higher dose. In three patients given 120M cells -- compared to 80M and 40M in other patients -- there was one non-responder, with two remissions lasting less than three months.”⁵⁹

VII. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

142. During the Class Period, the market for Caribou's common stock was traded in an efficient market for the following reasons, among others:

(a) The Company's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient electronic stock market;

(b) As a regulated issuer, the Company filed periodic public reports with the SEC

(c) The Company regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) The Company was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their

⁵⁹ Block, Jonathan, *Caribou Biosciences down 23% on stock offering, lymphoma data*, SEEKING ALPHA (Jul. 14, 2023 2:12PM ET), <https://seekingalpha.com/news/3987777-caribou-biosciences-down-23-stock-offering-lymphoma-data> (“7/14/23 SA Article”).

1 respective brokerage firms. Each of these reports was publicly available and entered the public
2 marketplace.

3 143. As a result of the foregoing, the market for Caribou's common stock promptly
4 digested current information concerning the Company from all publicly available sources and
5 reflected such information in the prices of the Company's stock. Under these circumstances, all
6 purchasers of the Company's common stock during the Class Period suffered similar injury
7 though their purchase of the Company's common stock at artificially inflated prices and a
8 presumption of reliance applies.

9 144. Alternatively, Plaintiffs and the other Class members are entitled to the
10 presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State*
11 *of Utah v. U.S.*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as the Exchange Act Defendants omitted
12 material information in their Class Period statements in violation of a duty to disclose such
13 information, as detailed above.

14 **VIII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS**
15 **CAUTION DOCTRINE**

16 145. The statutory safe harbor or bespeaks caution doctrine applicable to forward-
17 looking statements under certain circumstances does not apply to any of the false and misleading
18 statements pleaded in this Complaint. The statements alleged to be false or misleading herein all
19 relate to then-existing facts and conditions. In addition, to the extent certain of the statements
20 alleged to be false or misleading may be characterized as forward-looking, they were not
21 adequately identified as forward-looking statements when made, and there were no meaningful
22 cautionary statements identifying important facts that could cause actual results to differ
23 materially from those in the purportedly forward-looking statements.

24 146. To the extent that the statutory safe harbor does apply to any forward-looking
25 statements pleaded herein, the Exchange Act Defendants are liable for those false forward-
26 looking statements because at the time each of those forward-looking statements was made, each
27 Exchange Act Defendant had actual knowledge that the particular forward-looking statement

was materially false or misleading. The Exchange Act Defendants are liable for the statements pleaded because, at the time each of those statements was made, they each knew the statement was false, and the statement was authorized and/or approved by an executive officer and/or director of Caribou who knew that such statement was false when made.

IX. CAUSES OF ACTION UNDER THE EXCHANGE ACT

COUNT I

Violations of § 10(b) and Rule 10b-5 Against All Exchange Act Defendants

147. Plaintiffs repeat and re-alleges each and every allegation contained above as if fully set forth herein.

148. During the Class Period, the Exchange Act Defendants disseminated or approved the materially false and misleading statements specified above, which they knew, or were deliberately reckless in not knowing, were misleading. These statements were false and misleading because they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

149. Exchange Act Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact/and or omitted to state material facts necessary to make the statements made not misleading; and (3) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

150. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiffs and the Class would not have purchased the Company's common stock at the prices they paid—or at all—if they had been aware that the market prices had been artificially and falsely inflated by Exchange Act Defendants' misleading statements.

COUNT II

Violation of § 20(a) Against the Exchange Act Individual Defendants

1 151. Plaintiffs repeat and reallege each and every allegation contained above as if fully
2 set forth herein.

3 152. During the Class Period, the Exchange Act Individual Defendants participated in
4 the operation and management of Caribou, and conducted and participated, directly and
5 indirectly, in the conduct of Caribou's business affairs. Because of their senior positions, they
6 knew the adverse nonpublic information about Caribou's misstatement of income and expenses
7 and false financial statements.

8 153. As officers and/or directors of a publicly owned company, the Exchange Act
9 Individual Defendants had a duty to disseminate accurate and truthful information with respect
10 to Caribou's financial condition and results of operations, and to correct promptly any public
11 statements issued by Caribou which had become materially false or misleading.

12 154. Because of their positions of control and authority as senior officers, the Exchange
13 Act Individual Defendants were able to, and did, control the contents of the various reports, press
14 releases and public filings which Caribou disseminated in the marketplace during the Class
15 Period concerning Caribou's results of operations. Throughout the Class Period, the Exchange
16 Act Individual Defendants exercised their power and authority to cause Caribou to engage in the
17 wrongful acts complained of herein. The Exchange Act Individual Defendants therefore, were
18 "controlling persons" of Caribou within the meaning of § 20(a). In this capacity, they participated
19 in the unlawful conduct alleged which artificially inflated the market price of Caribou securities.

20 155. Each Exchange Act Individual Defendants, therefore, acted as a controlling
21 person of Caribou. By reason of their senior management positions and/or being directors of
22 Caribou, each Exchange Act Individual Defendants had the power to direct the actions of, and
23 exercised the same to cause, Caribou to engage in the unlawful acts and conduct complained of
24 herein. Each Exchange Act Individual Defendants exercised control over the general operations
25 of Caribou and possessed the power to control the specific activities which comprise the primary
26 violations about which Plaintiffs and the other members of the Class complain.

27

1 156. By reason of such conduct, the Exchange Act Individual Defendants are liable
2 pursuant to § 20(a).

3 **X. PLANTIFFS' SECURITIES ACT CLAIMS**

4 157. The claims alleged in this Section are based on principles of negligence and strict
5 liability. Only the allegations in ¶¶1-13, 22-23, 26-27, and 32-37, *supra*, are realleged in this
6 Section pertaining to the Securities Act claims and only such paragraphs apply to the Securities
7 Act Claims.

8 158. None of the preceding allegations in the Complaint from ¶¶14-21, 24-25, and 28-
9 156 that are set forth in the Class's claims under §§ 10(b) and 20(a) of the Exchange Act apply
10 to these Securities Act claims.

11 159. In this Section, Plaintiffs assert a series of strict-liability and negligence claims
12 under §§ 11 and 15 of the Securities Act on behalf of all persons or entities who purchased or
13 otherwise acquired Caribou common stock in or traceable to IPO and pursuant to the Offering
14 Documents.

15 160. Each Defendant is statutorily liable under § 11 of the Securities Act for the
16 materially inaccurate statements contained in the Offering Documents. Additionally, Plaintiffs
17 assert control person liability under § 15 of the Securities Act against the Individual Defendants.

18 161. The Securities Act claims are based on the fact that Offering Documents
19 contained untrue statements of material fact and omitted material facts about Caribou's business
20 and operations. As described below, the Securities Act claims against the Securities Act
21 Defendants are premised upon the undisclosed facts set forth below, and others, which, rendered
22 materially untrue and incomplete the statements contained in the Offering Documents.

23 162. The Securities Act claims against Defendants are also premised upon their
24 negligent failure to conduct a reasonable due-diligence investigation into the accuracy and
25 completeness of the representations contained in the IPO Materials. Had Defendants not acted
26 negligently, and had they conducted reasonable due-diligence investigations before the IPO, they
27

1 would have uncovered that the Registration Statement contained untrue statements of fact and
2 omitted material facts.

3 163. Plaintiffs' Securities Act claims are not based on any knowing or deliberately
4 reckless misconduct on the part of the Defendants. Thus, for purposes of Counts III-IV below,
5 Plaintiffs' claims do not sound in fraud, and Plaintiffs expressly disclaim any allegations of fraud
6 or intentional misconduct in connection with these nonfraud claims, which are pleaded separately
7 in this Complaint from Plaintiffs' Exchange Act claims.

8 **A. Jurisdiction and Venue for Plaintiffs' Securities Act Claims**

9 164. Counts Three and Four arise under §§ 11 and 15 of the Securities Act, 15 U.S.C.
10 §§77k, 771(a)(2) and 77o.

11 165. This Court has jurisdiction over the subject matter of this action pursuant to 28
12 U.S.C. §1331 and § 22 of the Securities Act because this is a civil action arising under U.S. laws.

13 166. Venue is proper in this Judicial District pursuant to § 22 of the Securities Act and
14 28 U.S.C. § 1391(b)-(d). Specifically, Caribou is headquartered in this Judicial District,
15 Defendants conduct business in this Judicial District, and a significant portion of Defendants'
16 activities took place within this Judicial District.

17 167. In connection with the acts, transactions, and conduct alleged herein, Defendants,
18 directly or indirectly, used the means and instrumentalities of interstate commerce, including,
19 but not limited to, the U.S. mail, interstate telephone and other electronic communications, and
20 the facilities of the NASDAQ, a national securities exchange.

21 **B. Additional Securities Act Defendants**

22 1. Director Defendants

23 168. Defendant Ryan Fischesser ("Fischesser") served as Caribou's Vice President
24 ("VP") of Finance and Controller since 2022. Prior to Caribou, he co-founded the accounting
25 firm BHLF LLP where he provided audit and outsourced accounting services to clients, including
26 in the life sciences industry. He earned his B.S. degree in Business Administration with an
27

1 emphasis in financial services from Saint Mary's College of California and is a licensed Certified
2 Public Accountant. Fischesser signed or authorized the signing of the Registration Statement
3 filed with the SEC.

4 169. Defendant Scott Braunstein ("Braunstein") has served as a Director of Caribou at
5 all relevant times. He also currently serves as Chairman of the Board and CEO of Marinus
6 Pharmaceuticals, a company dedicated to the development of innovative therapeutics to treat
7 seizure disorders, and a board member of Trevena, Inc. Prior to joining Marinus Pharmaceuticals,
8 he served as Chief Strategy Officer and Chief Operating Officer at Pacira Pharmaceuticals, Inc.
9 In addition, he has held the role of operating partner at Aisling Capital since 2015 and earlier in
10 his career, Scott served as a healthcare Portfolio Manager at Everpoint Asset Management and
11 spent 12 years with J.P. Morgan Asset Management as a Healthcare Analyst and Managing
12 Director on the U.S. equity team and as portfolio manager of the J.P. Morgan Global Healthcare
13 Fund. He further previously served as a board member of Constellation Pharmaceuticals
14 (acquired by MorphoSys AG in July 2021), Ziopharm Oncology, Inc., Esperion Therapeutics,
15 Inc., and Protara Therapeutics, Inc. He received his medical degree from the Albert Einstein
16 College of Medicine and his B.S. from Cornell University. Braunstein signed or authorized the
17 signing of the Registration Statement filed with the SEC.

18 170. Defendant Andrew Guggenhime ("Guggenhime") has served as a Director of
19 Caribou at all relevant times. He is also the President and CFO at Vaxcyte, Inc., responsible for
20 leading its finance, corporate development and strategy, investor relations, corporate
21 communications, human resources, IT, and facilities functions, and helped to lead its initial
22 public offering in 2020. Prior to joining Vaxcyte, Guggenhime served as CFO of Dermira, Inc.,
23 where he successfully led a series of private, public, and alternative financings and helped scale
24 the company, including through its transition into a commercial-stage organization. Previously,
25 Guggenhime served as CFO at Calistoga Pharmaceuticals, Inc., which was acquired by Gilead
26 Sciences, Inc., and Facet Biotech Corporation, which was acquired by Abbott Laboratories.

1 Earlier in his career, he served as CFO of PDL BioPharma, Inc. until Facet Biotech was spun off
 2 from it. Prior to joining Facet Biotech, he served as CFO for Neoforma, Inc., which was acquired
 3 by Global Healthcare Exchange, LLC. He earned his B.A. in international politics and economics
 4 from Middlebury College and his M.B.A. from the J.L. Kellogg Graduate School of Management
 5 at Northwestern University. Guggenhime signed or authorized the signing of the Registration
 6 Statement filed with the SEC.

7 171. Defendant Jeffrey Long-McGie (“Long-McGie”) served as a Director of Caribou
 8 at the time of the IPO but resigned from its Board as of July 27, 2021, in connection with the
 9 closing of the offering. He is a managing director of Ridgeback Capital Investments and a board
 10 member of Quell Therapeutics. Long-McGie signed or authorized the signing of the Registration
 11 Statement filed with the SEC.

12 172. Defendant Natalie R. Sacks (“Sacks”) has served as a Director of Caribou at all
 13 relevant times. Previously, she served in development and executive leadership roles at multiple
 14 companies including at Onyx Pharmaceuticals (acquired by Amgen), Harpoon Therapeutics,
 15 Aduro, Exelixis, and Cell Genesys. She also serves on the board of directors of Zymeworks and
 16 STipe Therapeutics. She earned her B.A. in Mathematics from Bryn Mawr College, her M.S. in
 17 Biostatistics from Harvard University School of Public Health, and her M.D. from the University
 18 of Pennsylvania School of Medicine. Sacks signed or authorized the signing of the Registration
 19 Statement filed with the SEC.

20 173. Defendants Fischerrer, Braunstein, Guggenhime, Long-McGie, and Sacks are
 21 collectively referred to as the “Director Defendants.” The Director Defendants and the Exchange
 22 Act Individual Defendants are collectively referred to as the “Individual Defendants”)

23 174. As directors, executive officers, and/or major shareholders of the Company, the
 24 Individual Defendants participated in the solicitation and sale of Caribou common stock in the
 25 IPO for their own benefit and the benefit of Caribou. The Securities Act Individual Defendants
 26 were key members of the IPO working group and executives of Caribou who pitched investors
 27

1 to purchase the shares sold in the IPO.

2 2. Underwriter Defendants

3 175. Defendant Bank of America Securities, Inc. is a financial services company
4 located in New York. BofA served as an underwriter for the IPO, helping to draft and disseminate
5 the Registration Statement and to solicit investors to purchase Caribou common stock pursuant
6 thereto.

7 176. Defendant Citigroup Global Markets, Inc. is a financial services company located
8 in New York. Citigroup served as an underwriter for the IPO, helping to draft and disseminate
9 the Registration Statement and to solicit investors to purchase Caribou common stock pursuant
10 thereto.

11 177. Defendant SVB Securities LLC, which changed its name from SVB Leerink LLC
12 on February 1, 2022, is a financial services company located in New York. SVB served as an
13 underwriter for the IPO, helping to draft and disseminate the Registration Statement and to solicit
14 investors to purchase Caribou common stock pursuant thereto.

15 178. The Individual Defendants, the Underwriter Defendants and Caribou are
16 sometimes collectively, in whole or in part, referred to herein as “Defendants.”

17 179. The Underwriter Defendants agreed to purchase and sell shares of Caribou
18 common stock to the public as follows: BofA - 6,935,000 shares; Citigroup - 6,365,000 shares;
19 SVB - 5,700,000 shares.

20 180. The Underwriter Defendants collectively received over \$24.4 million in
21 underwriting fees and discounts for underwriting the IPO.

22 **C. Securities Act Defendants’ Violations of the Securities Act**

23 1. Caribou’s Blockbuster IPO

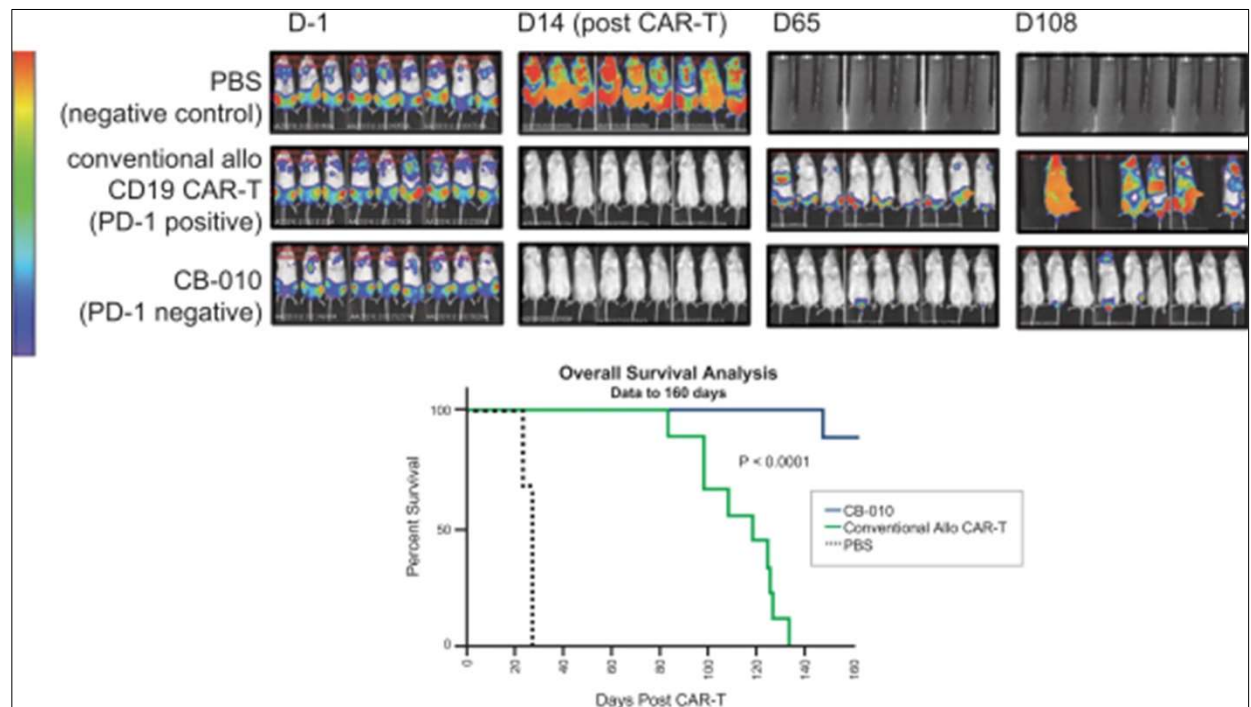
24 181. In connection with its IPO, Caribou filed the Registration Statement on Form S-
25 1 with the SEC on July 1, 2021. Caribou subsequently amended the Registration Statement twice
26 and requested that the SEC declare it effective on an accelerated basis. Consistent with its
27

standard practice, the SEC acceded to this request and on July 22, 2021, the Registration Statement went into effect.

182. As a result, on July 23, 2021, pursuant to the Registration Statement, Caribou's common stock began publicly trading on the NASDAQ. That same day, Caribou filed the Prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement.

183. Pursuant to the Offering Documents, Caribou issued 19 million shares of common stock to the public at the Offering price of \$16.00 per share for proceeds of \$282.72 million to the Company, before expenses, and after applicable underwriting discounts. The IPO thus valued Caribou at a whopping \$907.3 million.

184. The Offering Documents touted CB-010 as the "*first* clinical-stage allogeneic anti-CD19 CAR-T cell therapy" and represented that Caribou "ha[s] *demonstrated* in preclinical models that the PD-1 knockout [effect of CB-010] improves the persistence of antitumor activity," and from those models, provided mice tumor activity up to day 108 and survival data up to day 160 or 5.3 months:



1 185. The Offering Documents further represented that “by day 108 following dosing,
2 half the mice treated with the conventional allogeneic CD19 CAR-T cell therapy had expired
3 from their recurrent tumor burden, and the surviving mice in that cohort had metastatic disease.
4 In contrast, by day 108 following dosing, all of the CB-010-treated mice were alive and roughly
5 half had no detectable tumor burden . . . all of the mice treated with the conventional allogeneic
6 CD19 CAR-T cells had succumbed to their tumors by approximately day 135, while all but one
7 of the CB-010 treated mice were still alive by day 160.”

8 186. With respect to the purported durability of CB-010’s treatment effect, the
9 Offering Documents specifically stated, in relevant part, that “preclinical in vivo data from
10 experiments conducted in mouse xenograft models submitted as part of our CB-010 IND
11 [Application] **demonstrate** that knocking out PD-1 leads to a significant increase in the durability
12 of antitumor activity and therefore overall mouse survival.”

13 187. And with respect to the purported efficacy of CB-010’s treatment, the Offering
14 Documents touted that “We use our chrDNA technology to **enhance, or armor**, our cell
15 therapies by creating additional genomic edits to improve persistence of antitumor activity.”

16 188. The Registration Statement also disclosed as a “risk factor” the names of
17 Caribou’s competitors. While maintaining that its technology was superior, it disclosed the
18 names of other companies developing CRISPR-based technologies:

19 Compared to first generation genome-editing approaches, our chrDNA platform
20 has shown improved specificity, a reduction in off-target edits and translocations
21 and advanced capability to perform multiplexed edits, in particular multiplexed
22 insertions. While we believe that our scientific expertise, novel technology, and
23 intellectual property position offer competitive advantages, we face competition
24 from multiple other genome-editing technologies and companies. Other companies
25 developing CRISPR-based technologies include, among others, Beam
26 Therapeutics Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Intellia
27 Therapeutics, Inc., Metagenomi Technologies, LLC, Poseida Therapeutics, Inc.,
and Scribe Therapeutics, Inc. Companies developing other genome-editing
technologies include, among others, Allogene Therapeutics, Inc., bluebird bio, Inc.,
Collectis S.A., Precision BioSciences, Inc., and Sangamo Therapeutics, Inc.

We believe that our CAR-T cell therapy product candidates have the potential to offer a superior product to patients due to genome edits we make to improve their

persistence with the goal of extending robust CAR-T cell antitumor activity in patients.

189. Analysts focused on the Offering Documents’ statements about the Company’s “demonstrat[ion] in preclinical models”⁶⁰ and “refer[ence] to its process as ‘armoring’ the cells”⁶¹ in promoting the IPO.

190. Further, the Registration Statement noted that the Company’s *in vitro* studies showed that “CB-010 cells demonstrate *dose-dependent* and robust cytotoxic activity at a range of effector-to-target ratios compared to negative control cells.” Accordingly, investors understood that CB-010’s treatment effect would be more durable as doses were escalated.

2. Unbeknownst to Investors, Caribou’s Competitors Had Already Achieved Results Comparable to Early Autologous Car-T Trials.

191. According to the Offering Documents, the Company’s preclinical data showed statistically significant improvement in survival of mice that received CB-010 treatment compared to control groups that did not. The preclinical study involved engrafting mice with acute leukemia, waiting 23 days before commencing treatment, and then testing the mice in three separate treatment groups as follows: (1) a control saline; (2) conventional allogeneic CD19 CAR-T cells, *i.e.* T cells with the anti-CD19 CAR used in CB-010 inserted into the TRAC locus, but without the PD-1 knockout, or (3) CB-010.

192. Although preclinical studies on mice are common, scientists have noted that they are limited in their ability to mimic the extremely complex process of human carcinogenesis, physiology, and progression.⁶²

193. On September 8, 2020, Caribou announced that the FDA had cleared the Company’s IND Application for CB-010, which had included its preclinical mice study in its data package. The Company further announced that it would begin clinical trials of CB-010.

⁶⁰ See 7/22/21 SA Article.

⁶¹ See 7/27/21 Motley Article.

⁶² See 7/10/23 Eureka Article.

1 194. On October 21, 2020, a Caribou competitor also focusing on allogeneic cell
2 therapy, CRISPR Therapeutics AG (“CRISPR”) released top-line results from its ongoing Phase
3 1 CARBON trial of CTX110, an allogeneic CAR-T cell therapy targeting CD19+ B-cell
4 malignancies. The results showed CR rates of 33%, 50%, and 100% at dose levels 2, 3, and 4,
5 respectively, at three months. These results “show[ed] dose dependent efficacy and response
6 rates that are comparable to the early autologous CAR-T trials.”⁶³

7 195. On June 4, 2021, Allogene released updated data for its allogeneic gene-editing
8 treatment for non-Hodgkin lymphoma, which showed a six-month CR rate of 36% in CAR T
9 naïve LBCL patients treated with ALLO-501 and a “CR rate of 50% across [LBCL and follicular
10 lymphoma] histologies in CAR T naïve patients on par with autologous CAR T therapies.”⁶⁴

11 3. Unbeknownst to Investors, CB-010’s Treatment Effect Was Not as
12 Durable or Dose-Dependent as Caribou’s Preclinical Data Purportedly
13 Indicated.

14 196. The Securities Act Defendants negligently misled investors regarding the
15 durability assumptions for CB-010 which were based on Caribou’s preclinical data.

16 197. At the time of the IPO, the Securities Act Defendants negligently did not disclose
17 what the Company’s mice data showed regarding overall tumor burden or cancer progression
18 after Day 108 and survivability of the mice after day 160 or failed to continue to study mice data
19 past 5.3 months. Yet the Securities Act Defendants assured investors that Caribou’s preclinical
20 data signaled durability.

21 198. In addition, two months prior to the IPO, a Phase 1 clinical trial sponsored by
22 Gracell concluded. Gracell is a Chinese company publicly traded on the NASDAQ which has “a

23 ⁶³ See 10/21/20 Article (“Joseph McGuirk, professor of Medicine and division director of
24 Hematologic Malignancies and Cellular Therapeutics at the University of Kansas Medical Center
25 and investigator in the Phase I CARBON trial, noted, ‘From this early data read-out, CTX110 has
26 shown dose-dependent efficacy and response rates that are comparable to the early autologous
27 CAR-T trials. Furthermore, CTX110 had an acceptable safety profile, which could make CAR-
Ts more widely accessible.’”).

⁶⁴ 6/4/21 Allogene News.

rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential to overcome major industry challenges that persist with conventional CAR-T therapies, including lengthy manufacturing time, suboptimal production quality, high therapy cost and lack of effective CAR-T therapies for solid tumors.”⁶⁵

199. Like Caribou’s CB-010 – which purportedly was the first ever allogeneic CAR-T therapy that knocked out PD-1 – the Gracell clinical trial tested a treatment that knocked out PD-1 in relapsed cancer patients (“Gracell Trial”). The Securities Act Defendants omitted to disclose the Gracell Trial or negligently failed to learn of it, given the similarity between the two treatments and the Company’s focus on its competitors.

200. The Gracell Trial only generated a response in 2 out of 15 patients. As the researchers explained, the “poor clinical response implies that CAR-T cell-intrinsic modification alone, for example, *knocking out PD-1 in CAR-T cells, may not be enough to induce promising outcomes in the treatment of patients.*”⁶⁶ The Securities Act Defendants did not disclose the results of or the existence of the Gracell Trial in the Offering Documents.

4. As Information Incorrectly Stated in, and Omitted from, the Registration Statement Is Gradually Disclosed, the True Value of Caribou Common Stock Is Revealed.

201. On June 10, 2022, during pre-market hours, Caribou issued a press release reporting “Positive Additional Data from CB-010 Allogeneic CAR-T Cell Therapy Phase 1 ANTLEER Trial at the [EHA] 2022 Hybrid Congress.”⁶⁷ Among other results, that press release reported that “[a]t 6 months following the single dose of CB-010, **40% of patients remained in CR (2 of 5 patients) as of the May 13, 2022 data cutoff date.**”

202. And Jacob Plieth of Evaluate Vantage pointed out later that day:⁶⁸

Caribou has hailed its Crispr-edited CD19-targeting lead project, CB-010, as the

⁶⁵ Gracell Biotechnologies Inc., *Corporate Profile*, <https://ir.gracellbio.com/>.

⁶⁶ 2021 Wang Study.

⁶⁷ June 2022 Press Release.

⁶⁸ 6/10/22 EV Article.

1 first ever off-the-shelf Car-T to show a 100% complete response rate.
 2 **Unfortunately, this does not tell the whole story: as the group’s EHA poster
 revealed today, few of the remissions are durable.**

3 **Caribou thus appears to be the latest allogeneic Car-T player to run into the
 4 problem of relapse, after this issue last year derailed Allogene, Crispr
 Therapeutics and Precision Biosciences.**

* * *

5 [B]y six months three of the six patients relapsed with progressive disease. Two
 6 of the three remaining CRs were ongoing beyond six months, and Caribou added
 7 that the first patient treated remained in CR at their 12-month scan, after the
 8 abstract’s cutoff date. All six subjects received the first dose level of 40 million
 lymphoma, a relatively slow-growing disease.

9 203. This observed tapering-off of CR after treatment with CB-010 understandably
 10 prompted investor concern over Caribou’s ability to demonstrate the durability of the CB-010
 11 treatment. For example, also on June 10, 2022, online investor news resource *Seeking Alpha*
 12 reported that “Caribou [was] in selloff after [the] data for cancer candidate [CB-010]” because
 13 “only two patients . . . remained on CR as of the May [13, 2022] data cutoff.”⁶⁹ Similarly, a
 14 Bloomberg Intelligence analyst wrote that CB-010 “showed lower-than-desired durability, with
 15 a [CR] in two out of five patients at six months[;]” and an SVB Securities analyst wrote that the
 16 update “has bears [i.e., pessimistic investors] arguing questions of durability of CR’s among
 17 patients with the most aggressive disease[.]”

18 204. On this news, Caribou’s stock price fell \$3.62 per share, or 41.51%, to close at
 19 \$5.10 per share on June 13, 2022 on heavy trading volume, damaging investors.

20 205. Then, on July 13, 2023, Caribou reported “long-term follow-up data from the dose
 21 escalation portion of the ongoing ANTLER Phase 1 trial,” including that in three subjects given
 22 120 million cells, there was one non responder (Caribou’s first) and two remissions lasting less
 23 than three months. Patients thus continued relapsing despite CB-010 being dosed higher,
 24 confirming the Company’s inability to demonstrate long-term durability.

25
 26
 27 ⁶⁹ 6/10/22 SA Article.

206. As Plieth of Evaluate Vantage pointed out later that day:⁷⁰

With allogeneic Car-T projects struggling to yield lasting responses, six-month durability has emerged as something of a minimum for a patient's remission to hit to be considered real. And yesterday Caribou joined Allogene in claiming that around half of lymphoma subjects treated with its project can develop responses that are maintained to this time point.

The 50% bar is relevant because it broadly matches what autologous Car-T therapies are capable of in this setting, and with the convenience of an off-the-shelf therapy the possible advantages are obvious. However, Caribou's data, from the latest iteration of the Antler study of CB-010, make it clear that relapses will continue to be watched closely.

* * *

More puzzling is the fact that patients continue relapsing in spite of CB-010 being dosed higher. Four of the five new responders had been given 80 million cells, but in three subjects given 120 million cells there was one non-responder – Caribou’s first – and two remissions lasting less than three months.

207. On this news, Caribou's stock price fell \$1.84 per share, or 22.6%, on heavy trading to close at \$6.30 per share on July 14, 2023, further damaging investors. Concerns that Caribou would not be able to demonstrate that the CB-010 treatment was durable even at higher doses thus were confirmed. As *Seeking Alpha* reported that same day, the Company was "down 23% in Friday trading after announcing following Thursday's closing bell ... phase 1 data on a non-Hodgkin's lymphoma CAR-T candidate[.]" and "[o]ne peculiarity in the data, pointed out by Evaluate Vantage's Jacob Plieth, was that some patients are still relapsing despite receiving a higher dose. In three patients given 120M cells -- compared to 80M and 40M in other patients -- there was one non-responder, with two remissions lasting less than three months."⁷¹

5. The Registration Statement Contained Untrue Statements of Material Fact and Material Omissions in Violation of § 11 of the Securities Act

208. The Registration Statement contained untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading under the circumstances under which they were made.

⁷⁰ 7/14/23 EV Article.

⁷¹ 7/14/23 SA Article.

209. In touting CB-010's PD-1 knockout effect and the treatment's attendant clinical prospects, the Registration Statement stated, *inter alia*:

We use Cas9 chRDNA guides to make three edits to manufacture CB-010. We introduce, with high efficiency and specificity, the gene encoding the CD19-specific CAR into the gene encoding the T cell receptor alpha constant, or TRAC, a component of the native T cell receptor, or TCR. This simultaneously integrates the CD19 CAR site-specifically into the T cell genome and eliminates TCR expression to reduce the risk of graft versus host disease, or GvHD. ***We also knock out the gene encoding the PD-1 protein in these cells to boost the persistence of CAR-T cell antitumor activity. We believe that the PD-1 knockout has the potential to reduce the likelihood of rapid tumor recurrence and potentially confer a better therapeutic index compared to other allogeneic CAR-T cells. To our knowledge, CB-010 is the first allogeneic CAR-T cell therapy with a PD-1 knockout in clinical studies*** and it is being evaluated in our open-label, multicenter ANTLEER phase 1 clinical trial in the United States in adults with relapsed or refractory B cell non-Hodgkin lymphoma (NCT04637763). We have dosed the first patient in this clinical trial.

210. The statements in ¶209, *supra*, in bold and italics were false and materially misleading and/or omitted to state material facts necessary to make them not misleading when made because the Securities Act Defendants failed to disclose: (i) the existence of the Gracell Trial, which meant that Caribou was not the first to use the PD-1 knockout in an allogeneic CAR-T cell treatment; and (ii) that the Gracell Trial had already demonstrated that knocking out the PD-1 protein was not linked to enhanced durability or clinical performance, calling into question the purportedly unique advantage of CB-010 as a treatment.

211. In the Registration Statement, the Securities Act Defendants also touted PD-1 knockout as a solution to the problem that allogeneic treatments have had with persistence, due to the human immune system attacking the foreign donor cells:

Our first lead product candidate, CB-010, is, to our knowledge, the first clinical-stage allogeneic anti-CD19 CAR-T cell therapy with PD-1 removed from the CAR-T cell surface by a genome-edited knockout of the PDCD1 gene. ***We have demonstrated in preclinical models that the PD-1 knockout improves the persistence of antitumor activity by disrupting a pathway that leads to rapid T cell exhaustion.*** We have dosed the first patient in our ANTLEER phase 1 clinical trial for CB-010, a study in patients with relapsed or refractory B cell non-Hodgkin lymphoma, with initial data expected in 2022.

212. The statement identified in ¶211, *supra*, in bold and italics was false and materially misleading and/or omitted to state material facts necessary to make it not misleading when made because Caribou then lacked the clinical data to show that the PD-1 knockout would improve allogeneic durability given that the pre-clinical data in the Registration Statement did not go past 5.3 months and given that 6 months is the minimum threshold for durability.

213. In the Registration Statement, the Securities Act Defendants claimed Caribou had a competitive edge over other companies developing allogeneic therapies:

The genome-editing technologies currently used in the allogeneic cell therapy field generally have limited efficiency, specificity, and versatility for performing the multiple, precise genomic edits necessary to address insufficient persistence. Our chRDNA technology is designed to address these genome-editing limitations and improve cell therapy activity. By applying this approach to allogeneic cell therapies, we believe we can unlock their full potential by improving upon their effectiveness and durability.

214. The statements in ¶213, *supra*, in bold and italics were false and materially misleading and/or omitted to state material facts necessary to make them not misleading when made because the Exchange Act Defendants failed to disclose that Caribou's competitors in the allogeneic gene-editing space, including Allogene and CRISPR, had already published data that showed comparable or better durability data than approved autologous therapies, and Caribou lacked data to show that its technology was superior.

215. In the Registration Statement, the Securities Act Defendants also touted Caribou's preclinical data from a study performed in mice, presenting data for 160 days of study in which days in which mice were given either a control injection, conventional allogeneic CD19 CAR-T cells without PD-1 knockout, or CB-010 with the PD-1 knockout. The Registration Statement stated the following with respect to CB-010's clinical prospects based on the mice study:

In our preclinical studies, we demonstrated that the removal of the PD-1 checkpoint from the CB-010 CAR-T cells provided a statistically significant survival advantage in mice bearing robust and metastatic B cell tumors.

Overall, our data demonstrate that the removal of the PD-1 checkpoint from the

CB-010 CAR-T cells provided a statistically significant survival advantage in mice bearing robust and metastatic B cell tumors. Our data suggest that the PD-1 knockout may have led to a more robust debulking of the tumor by CB-010 during the early part of the study compared to the conventional allogeneic CD19 CAR-T cells, leading to a reduction in the recurrence of the tumor cells. Based on these data, we believe CB-010 has the potential for a better therapeutic index compared to other allogeneic CAR-T cells. If a lower dose of CB-010 has meaningful activity in the clinical setting, it would lead to several potential advantages including limited toxicity, increased numbers of doses per manufacturing run, and a reduced cost of goods.

216. The statements in ¶215, *supra*, in bold and italics were false and materially misleading and/or omitted to state material facts necessary to make them not misleading when made because the Securities Act Defendants omitted to disclose: (i) the existence of the Gracell Trial and the uncertainty about the clinical benefits of removing PD-1 checkpoints, as the Gracell Trial already demonstrated; and (ii) given that 6 months is the minimum threshold for durability, relying on 5.3 months of mice data would not be an indication of CB-010's durability in the ANTLE trial.

217. With specific respect to the purported durability of CB-010's treatment effect, as afforded by the PD-1 knockout strategy, the Registration Statement stated, in relevant part:

One of the approaches we deploy to increase the persistence of CAR-T cell antitumor activity is to remove PD-1 from the CAR-T cell surface We believe that knocking out PD-1 will maintain the CAR-T cells in a higher antitumor state for a longer period of time, and we believe this will result in greater initial tumor debulking in the patient which will lead to long-term durability of CAR-T cell antitumor activity *[O]ur preclinical in vivo data from experiments conducted in mouse xenograft models submitted as part of our CB-010 IND [Investigational New Drug Application] demonstrate that knocking out PD-1 leads to a significant increase in the durability of antitumor activity and therefore overall mouse survival.* To our knowledge, our lead product candidate [CB-010] is the first allogeneic CAR-T cell therapy in a clinical study with a PD-1 knockout, and we believe will drive the durability of allogeneic CAR-T cell antitumor activity.

218. The statement in ¶217, *supra*, in bold and italics was false and materially misleading and/or omitted to state material facts necessary to make it not misleading when made for the reasons set forth in ¶212, *supra*.

6. The Registration Statement Failed to Disclose Information Required to Be Disclosed Under SEC Regulation S-K

1 219. SEC Regulation S-K required the Securities Act Defendants to describe in the
 2 Registration Statement, “any known trends or uncertainties that have had or that the registrant
 3 reasonably expects will have a material impact ... on net sales or revenues or income from
 4 continuing operations.” 17 C.F.R. § 229.303(a)(3)(ii) (“Item 303”) (2017). “Disclosure is
 5 mandatory where there is a known trend or uncertainty that is reasonably likely to have a material
 6 effect on the registrant’s financial condition or results of operations.” SEC Release Nos. 33-8056;
 7 34-45321; FR-61.

8 220. The SEC has emphasized that Item 303’s disclosure requirements are “intended
 9 to give the investor an opportunity to look at the company through the eyes of management by
 10 providing both a short and long-term analysis of the business of the company” and “a historical
 11 and prospective analysis of the registrant’s financial condition ... with particular emphasis on the
 12 registrant’s prospects for the future.” S.E.C. Release No. 6835, 1989 WL 1092885, at *3, *17.
 13 Thus, “material forward-looking information regarding known material trends and uncertainties
 14 is required to be disclosed as part of the required discussion of those matters and the analysis of
 15 their effects.” *See* Comm’n Guidance Regarding Mgmt.’s Discussion and Analysis of Fin.
 16 Condition and Results of Operations, S.E.C. Release No. 8350, 2003 WL 22996757, at *11
 17 (December 19, 2003).

18 221. Item 303 affirmatively required the Securities Act Defendants to disclose the
 19 trends and uncertainties related to Caribou with a high degree of specificity to comply with
 20 Regulation S-K’s rigorous disclosure requirements. Yet the Securities Act Defendants omitted
 21 to disclose in the Registration Statement that at least two competitors had already demonstrated
 22 that their allogeneic CAR-T cell therapy had dose-dependent efficacy and response rates
 23 comparable to the early autologous CAR-T trials, so Caribou was not the first. And the Securities
 24 Act Defendants also concealed that a Phase 1 clinical trial in which PD-1 was knocked out in
 25 relapsed cancer patients had previously only generated a response in 2 out of 15 patients, leading
 26 the researchers leading that trial to conclude “that CAR-T cell-intrinsic modification alone, for
 27

1 example, knocking out PD-1 in CAR-T cells, may not be enough to induce promising outcomes
 2 in the treatment of patients.” Accordingly, it was misleading for Caribou to present its preclinical
 3 data as having “demonstrated” the durability of its allogeneic treatment effect any more or better
 4 than its competitors preclinical data had, and thus it had just as high or even higher risk of not
 5 receiving FDA approval. The Securities Act Defendants’ omissions thus concealed from
 6 investors an uncertainty about the commercial viability of the Company’s CB-010 therapy, and
 7 of the Company itself because its therapies all hinged on the same technology.

8 222. The Securities Act Defendants’ lack of disclosures also violated their affirmative
 9 disclosure duties imposed by Regulation S-K Item 105, which required them to include in the
 10 Registration Statement a “discussion of the most significant factors that make the offering
 11 speculative or risky.” 17 C.F.R. § 229.503(c) (2011). Item 105’s purpose is “to provide investors
 12 with a clear and concise summary of the material risks to an investment in the issuer’s securities.”
 13 Sec. Offering Reform, S.E.C. Release No. 8501, 2004 WL 2610458, at *86 (Nov. 3, 2004). The
 14 discussion of risk factors must be specific to the particular company and its operations, and must
 15 explain how the risk affects the company and/or the securities being offered. Generic or
 16 boilerplate attempts to disclose potential risks and shield oneself from liability do not tell
 17 investors how the specific risks could affect their investment. *See* Statement of the Comm’n
 18 Regarding Disclosure of Year 2000 Issues and Consequences by Pub. Cos., Inv. Advisers, Inv.
 19 Cos., & Mun. Sec. Issuers, 1998 WL 425894, at *14 (July 29, 1998).

20 223. Item 105 required the Securities Act Defendants to disclose the most significant
 21 risks that could adversely affect Caribou’s present or future business expectations and not just
 22 reiterate boilerplate, generic risks that could apply to virtually any other drug development or
 23 biopharmaceutical company.

24 224. The risk that CB-010 therapy would not prove durable in humans, given that
 25 knocking out the PD-1 in CAR-T cells had already shown to not be a promising outcome when
 26 used to treat human patients, was already likely to occur, and was likely to adversely affect the
 27

1 Caribou's present or future business expectations, and, in fact, did have a negative impact on its
2 business prospects, yet the Securities Act Defendants failed to disclose these specific risks in the
3 Registration Statement.

4 **D. Additional Facts Probative of Underwriter Defendants' Liability**

5 225. In addition, the Underwriter Defendants are liable for the false and misleading
6 statements in the Registration Statement under the Securities Act because of the following:

7 (a) The Underwriter Defendants are investment banking houses that specialize in,
8 among other things, underwriting public offerings of securities. They served as the
9 underwriters of the IPO and shared substantial fees from the IPO collectively.

10 (b) The Underwriter Defendants also obtained an agreement from Caribou that it
11 would indemnify and hold the Underwriter Defendants harmless from any liability under
12 the federal securities laws.

13 (c) Representatives of the Underwriter Defendants also assisted Caribou and its
14 management and directors in planning the IPO, and purportedly conducted an adequate
15 and reasonable investigation into the business and operations of the Company, an
16 undertaking known as a "due diligence" investigation. The Underwriters had to conduct
17 such due diligence to engage in the IPO. During the course of such investigation, the
18 Underwriter Defendants had continual access to internal, confidential, and current
19 corporate information concerning Caribou's most up-to-date operational and financial
20 results and prospects.

21 (d) In addition to availing themselves of virtually unlimited access to internal
22 corporate documents, agents of the Underwriter Defendants met with Caribou's lawyers,
23 management, and top executives and engaged in drafting sessions. During these sessions,
24 Caribou and the Underwriter Defendants reached an understanding on: (i) the strategy to
25 best accomplish the IPO; (ii) the terms of the IPO, including the price at which Caribou's
26 securities would be sold; (iii) the language to be used in the Registration Statement; (iv)

1 what disclosures about Caribou would be made in the Registration Statement; and (v)
 2 what responses would be made to the SEC in connection with its review of the
 3 Registration Statement. As a result of those constant contacts and communications
 4 between the Underwriter Defendants' representatives and Caribou's management and top
 5 executives, the Underwriter Defendants in the exercise of reasonable care should have
 6 known of Caribou's existing problems as detailed herein.

7 226. The Underwriter Defendants caused the Registration Statement to be filed with
 8 the SEC and declared effective in connection with the offers and sales of securities registered
 9 thereby, including those to Plaintiffs and other members of the Class.

10 **E. Causes of Action Under the Securities Act**

11 **COUNT III**

12 **Violations of § 11 of the Securities Act Against All Defendants**

13 227. Plaintiffs repeat and incorporate every allegation contained above as if fully set
 14 forth herein, except any allegation of fraud, recklessness, or intentional misconduct.

15 228. This Count is brought pursuant to § 11 of the Securities Act, 15 U.S.C. § 77k, on
 16 behalf of the Class, against Defendants.

17 229. The Offering Documents for the IPO were inaccurate and misleading, contained
 18 untrue statements of material facts, omitted to state other facts necessary to make the statements
 19 made not misleading, and omitted to state material facts required to be stated therein.

20 230. Caribou is the registrant for the IPO. Defendants named herein were responsible
 21 for the contents and dissemination of the Offering Documents.

22 231. As issuer of the shares, Caribou is strictly liable to Plaintiffs and the Class for the
 23 misstatements and omissions in the Offering Documents.

24 232. None of the Defendants named herein made a reasonable investigation or
 25 possessed reasonable grounds for the belief that the statements contained in the Registration
 26 Statement were true and without omissions of any material facts and were not misleading.

27 233. By reason of the conduct herein alleged, each Defendant violated or controlled a

1 person who violated § 11 of the Securities Act.

2 234. Plaintiffs acquired Caribou shares pursuant and/or traceable to the Offering
3 Documents for the IPO.

4 235. Plaintiffs and the Class have sustained damages. The value of Caribou securities
5 has declined substantially subsequent to and because of Defendants' violations.

6 **COUNT IV**

7 **Violations of § 15 Against the Individual Defendants**

8 236. Plaintiffs repeat and incorporate each and every allegation contained above as if
9 fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

10 237. This Count is asserted against the Individual Defendants and is based upon § 15
11 of the Securities Act, 15 U.S.C. § 77o.

12 238. The Individual Defendants, by virtue of their offices, directorship, and specific
13 acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of
14 Caribou within the meaning of § 15 of the Securities Act. The Individual Defendants had the
15 power and influence and exercised the same to cause Caribou to engage in the acts described
16 herein.

17 239. The Individual Defendants' positions made them privy to and provided them with
18 actual knowledge of the facts concealed from Plaintiffs and the Class.

19 240. By virtue of the conduct alleged herein, the Individual Defendants are liable for
20 the aforesaid wrongful conduct and are liable to Plaintiffs and the Class for damages suffered.

21 **XI. CLASS ACTION ALLEGATIONS APPLICABLE TO ALL CLAIMS**

22 241. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil
23 Procedure ("Rule") 23(a) and (b)(3) on behalf of a Class consisting of all persons and entities
24 other than Defendants that purchased or otherwise acquired: (a) Caribou common stock in the
25 IPO or purchased Caribou common stock thereafter in the stock market pursuant and/or traceable
26 to the Company's Offering Documents issued in connection with the IPO; and/or (b) Caribou
27

1 securities during the Class Period; and were damaged thereby. Excluded from the Class are
2 Defendants, the officers and directors of the Company, at all relevant times, members of their
3 immediate families and their legal representatives, heirs, successors, or assigns, and any entity
4 in which Defendants have or had a controlling interest.

5 242. The members of the Class are so numerous that joinder of all members is
6 impracticable. Throughout the Class Period, Caribou securities were actively traded on the
7 NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and
8 can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds
9 or thousands of members in the proposed Class. Record owners and other members of the Class
10 may be identified from records maintained by the Company or its transfer agent and may be
11 notified of the pendency of this action by mail, using the form of notice similar to that customarily
12 used in securities class actions.

13 243. Plaintiffs' claims are typical of the claims of the members of the Class, as all
14 members of the Class are similarly affected by Defendants' wrongful conduct in violation of
15 federal law that is complained of herein.

16 244. Plaintiffs will fairly and adequately protect the interests of the members of the
17 Class and have retained counsel competent and experienced in class and securities litigation.

18 245. Common questions of law and fact exist as to all members of the Class and
19 predominate over any questions solely affecting individual members of the Class. Among the
20 questions of law and fact common to the Class are:

- 21 (a) whether Defendants violated the federal securities laws;
- 22 (b) whether statements made by Defendants to the investing public in the Offering
23 Documents for the IPO, or during the Class Period, misrepresented material facts about
24 Caribou's preclinical and clinical studies and prospects;
- 25 (c) whether the Securities Act Individual Defendants negligently prepared the
26 Offering Documents for the IPO and, as a result, the Offering Documents contained
27

untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading, and were not prepared in accordance with the rules and regulations governing their preparation;

(d) whether the Exchange Act Individual Defendants caused Caribou to issue false and misleading financial statements during the Class Period;

(e) whether certain Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(f) whether the prices of Caribou securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and;

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

246. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in managing this action as a class action.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, prays for judgment and relief as follows:

(a) Determining that the instant action may be maintained as a class action under Rule 23, and certifying Plaintiffs as the Class Representative;

(b) Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

(c) Awarding Plaintiffs and the other Class members prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other court costs; and

(d) Awarding Plaintiffs and other Class members such other and further relief as the

1 Court may deem just and proper.

2 **XIII. JURY TRIAL DEMANDED**

3 Plaintiffs hereby demand a trial by jury.

4 Dated: September 18, 2023

Respectfully submitted,

5 **THE SCHALL LAW FIRM**

6 /s/ Ivy T. Ngo

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24 sfuks@rosenlegal.com

25 *Counsel for Plaintiffs and*
26 *Co-Lead Counsel for the Class*
27

Certification and Authorization of Named Plaintiff Pursuant to Federal Securities Laws

The individual or institution listed below (the "Plaintiff") authorizes and, upon execution of the accompanying retainer agreement by The Rosen Law Firm P.A., retains The Rosen Law Firm P.A. to file an action under the federal securities laws to recover damages and to seek other relief against Caribou Biosciences, Inc. The Rosen Law Firm P.A. will prosecute the action on a contingent fee basis not to exceed one-third of the recovery and will advance all costs and expenses. All payments of fees and expenses shall be made only after Court review and approval. The Caribou Biosciences, Inc. Retention Agreement provided to the Plaintiff is incorporated by reference herein and is effective, upon execution and delivery by The Rosen Law Firm P.A.

First Name: Carl
Middle Initial: D
Last Name: Cooper
Mailing Address: [REDACTED]
City: [REDACTED]
State: [REDACTED]
Zip Code: [REDACTED]
Country: USA
Phone: [REDACTED]
Email Address: [REDACTED]

Plaintiff certifies that:

1. Plaintiff has reviewed a complaint and authorized its filing or the filing of an amended complaint.
2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.
3. Plaintiff is willing to serve as a representative party on behalf of a class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff represents and warrants that he/she/it is fully authorized to enter into and execute this certification.
5. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.
6. Plaintiff has made no transaction(s) during the Class Period in the debt or equity securities that are the subject of this action except those set forth below:

Purchases:

Type of Security Common Stock	Buy Date 07/20/2022	# of Shares 325	Price per Share 7.8999
Type of Security Common Stock	Buy Date 09/02/2022	# of Shares 175	Price per Share 9.87
Type of Security Common Stock	Buy Date 09/09/2022	# of Shares 218	Price per Share 11.5313
Type of Security Common Stock	Buy Date 09/15/2022	# of Shares 782	Price per Share 13.1397
Type of Security Common Stock	Buy Date 01/03/2023	# of Shares 500	Price per Share 6.56

Sales:

Type of Security	Sale Date	# of Shares	Price per Share
Common Stock			

I have not sought to serve as a representative party on behalf of a class under the federal securities laws during the last three years, except if set forth below.

Not applicable

I declare and certify under penalty of perjury, under the laws of the United States of America, that the foregoing information is true and correct. **YES**

By Signing below and submitting this certification form electronically, I intend to sign and execute this certification pursuant to California Civil Code Section 1633.1, et seq. - and the Uniform Electronic Transactions Act and retain the Rosen Law Firm, P.A. to proceed on Plaintiff's behalf, on a contingent fee basis. **YES**

Date of signing: 03/24/2023 12:56:17 at Eastern Standard Time, USA